MINUTES OF 323rd MEETING OF REGISTRATION BOARD HELD ON 6th to 8th December, 2022

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

323rd meeting of Registration Board was held on 6th to 8th December, 2022 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad.

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

Following members attended the meeting:

1.	Ch. Zeeshan Nazir Bajar, Additional Director (PE&R), DRAP.	Member/ Secretary
2.	Lt. Gen.(R) Prof. Dr. Karamat A. Karamat (HI-M.SI-M), Former Surgeon General Pakistan.	Member
3.	Dr. Noor us Saba, Director, Biological Evaluation & Research Division, DRAP	Member
4.	Mr. Iftikhar A. Chaudhary, Hospital Pharmacist, Lahore	Member
5.	Mr. Hafeez ur Rehman, DTL, Rawalpindi	Member
6.	Dr. Imranullah Khan, Director, DTL, Peshawar	Member
7.	Mr. Muhammad Aslam, Deputy Draftsman-I, Ministry of law & Justice, Islamabad.	Member
8.	Mr. Ajmal Sohail Asif, Director, Division of QA&LT	Member
9.	Mrs. Muneeza Khan, Representative of Division of MD&MC	Member
10.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO	Member
11.	Maj. Gen. (R) Dr. Tahir Mukhtar Sayed, Inspector General (Hospitals), Fauji Foundation, Rawalpindi	Co-opted Member (Online)
12.	Dr. Qurban Ali, Ex-Director General, National Veterinary Laboratories, Islamabad	Co-opted Member
13.	Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o NFS&R	Co-opted Member

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Khalid Munir, Mr. Hamid Raza & Mr. Jalal-ud-Din (PPMA) and Mr. Ziaulhaq (PCDA) attended the meeting as observers.

Deputy Director (PEC) was assisted by respective Assistant Directors for presentation of the agenda. Director, BE&R was assisted by respective Additional Director and Assistant Directors for presentation of the agenda.

Item No. I: Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Farooq Aslam	Evaluator PEC-I
2.	Mr. Ammar Ashraf Awan	Evaluator PEC-II
3.	Mr. Muhammad Haseeb Tariq	Evaluator PEC-III
4.	Mst. Farzana Raja	Evaluator PEC-IV
5.	Mst. Iqra Aftab	Evaluator PEC-V
6.	Mr. Ishtiaq Shafique	Evaluator PEC-VI
7.	Mr. Muhammad Usman	Evaluator PEC-VIII
8.	Mr. Adil Saeed	Evaluator PEC-IX
9.	Mst. Najia Saleem	Evaluator PEC-X
10.	Dr. Farhadullah	Evaluator PEC-XI
11.	Mr. Shahid Nawaz	Evaluator PEC-XIII
12.	Mst. Saima Hussain	Evaluator PEC-XV
13.	Mr. Akbar Ali	Evaluator PEC-XVI
14.	Mr. Zia Ullah	Evaluator PEC-XVII
15.	Mr. Muneeb Ahmed	Evaluator PEC-XVIII
16.	Mst. Sana Kanwal	Evaluator PEC-XX
17.	Mr. Ahsan Hafiz	Assistant Director

Item No. I: Division of Pharmaceutical Evaluation & Registration

Item No. XIII: Agenda of Evaluator-X

1.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Doxycol Oral Powder 20%/500 MIU
	Composition	Each Kg Contains: Doxycycline Hyclate…20% w/w Colistin Sulphate…500MIU
	Diary No. Date of R& I & fee	Dy.No 13760 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	**Could not be verified in the applied strength**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• The firm has provided conversion of Colistin Sulphate MIU to mg. 1mg Colistin Sulphate contains 20000 IU **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit • Fee Rs. 7500/- for revision of finished product specifications.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
2.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Biofon Oral Powder 980mg/gm
	Composition	Each Gram Contains: Trichlorfon…980mg
	Diary No. Date of R& I & fee	Dy.No 13759 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	Trifon Powder of M/s S.J. & G. Fazul Ellahie (PVT) LTD., Karachi. (Reg. No. 049662)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection

		conducted on 12-12-2019.
	Remarks of the Evaluator [X]	
	Decision: Approved with innovator's specifications upto pack size of 1Kg. The firm shall submit fee of Rs. 7500/- for pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
3.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Amantagen 10 water soluble powder
	Composition	Each Kg Contains: **Amantadine HCl**…10% w/w
	Diary No. Date of R& I & fee	Dy.No 13784 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	As per Innovator specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5Kg: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	Antamits Water Soluble Powder of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078316)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	**Amantadine containing formulation for veterinary use could not be confirmed in any RRA.**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
4.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Oxycain Injection 200mg/20mg
	Composition	Each ml Contains: Oxytetracycline dihydrate…200mg Lidocaine HCl……20mg
	Diary No. Date of R& I & fee	Dy.No 13758 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	20ml, 50ml, 100ml: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	**Could not be confirmed in the applied strength and salt form**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• Initially, multiple pack sizes (20ml, 50ml, and 100ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml pack size**. • Upon clarification regarding proposed brand name that "Oxylag" has been mentioned on covering letter and "Oxycain" has been mentioned on both fee challan and Form-5, the firm has submitted proposed brand name "**Oxycain"** **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along

		with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for revision of finished product specifications.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
5.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	BG Vit Injection 100,000IU/40,000IU/40mg
	Composition	Each ml Contains: Vitamin A…100,000IU Vitamin D3…40,000IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 13769 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Growth promoter
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	20ml, 50ml, 100ml: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	Vital forte injection (100ml) of M/s Selmore.(Reg. No. 095649)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• Initially, multiple pack sizes (20ml, 50ml, and 100ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **100ml pack size**. • Upon clarification regarding proposed brand name since "BG VET Injection " is mentioned on covering letter and Form-5 while "BG VIT Injection " is mentioned on fee challan and Vital Forte injection is mentioned on master formula. The firm has submitted proposed brand name **BG Vit injection**
	Decision: Approved with innovator's specifications with 100ml pack size. The firm shall submit fee of Rs. 7500/- for pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
6.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Neodexa Injection 50mg/100,000 IU/50mg/0.5mg
	Composition	Each ml Contains: Kanamycin Sulphate…50mg Colistin Sulphate…100,000 IU Neomycin Sulphate…50mg Dexamethasone…0.5mg
	Diary No. Date of R& I & fee	Dy.No 13753 dated 07-03-2019 **Rs.20,000 dated 07-03-2019 (Fee challan is missing)**

	Pharmacological Group	Antibacterial/ Steroid
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	10ml, 30ml, 50ml, 100ml: As recommended by the PRC/ (M/o NHS, R&C)/ Federal Govt.
	Me-too status	KONO DEX Injection of M/s Alina Combine Pharmaceutical (Pvt) Ltd. Karachi (Reg. No. 052347)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• Original Fee challan is missing, provide original yellow copy for fee verification as per procedure adopted by the Registration Board in its 285th meeting. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provide conversion of Colistin Sulphate IU to mg. • Fee Rs.7,500/- for revision of finished product specifications. • Initially, multiple pack sizes (10ml, 30ml, 50ml, 100ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **50ml pack size**. **Shortcoming:** Evidence of approval of Liquid injection (Steroid) Section
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
7.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Bromogen Super Oral Solution 4% w/w
	Composition	Each ml Contains: Bromhexine HCl…4% w/**w**
	Diary No. Date of R& I & fee	Dy.No 13783 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: As recommended by the PRC/(M/o NHS, R&C)/ Federal Govt.
	Me-too status	Could not be confirmed in the applied strength
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for revision of finished product specifications. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

		• Correction in label claim is required since Each ml Contains: Bromhexine HCl…4% w/w is mentioned instead of w/v
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board.** • **Fee Rs.30,000/- for revision /pre-approval correction of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
8.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Bromogen 2% Solution
	Composition	Each ml Contains: Bromhexine Hcl…2% w/v
	Diary No. Date of R& I & fee	Dy.No 13786 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: As recommended by the PRC/(M/o NHS, R&C)/ Federal Govt.
	Me-too status	Could not be confirmed in the applied strength
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for revision of finished product specifications. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board.** • **Fee Rs.30,000/- for revision /pre-approval correction of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
9.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Enroflox Oral Liquid 10gm/50MIU
	Composition	Each 100ml Contains: Enrofloxacin…10Gm Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy.No 13761 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: As recommended by the

		PRC/(M/o NHS, R&C)/ Federal Govt.
	Me-too status	Coliflox Solution of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071082)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• The firm has provided conversion of Colistin Sulphate MIU to mg. 1mg Colistin Sulphate contains 20000 IU • Upon clarification regarding applied strength of Enrofloxacin, since Enrofloxacin…10Gm/100ml is mentioned in label claim on Form-5 while in master formula Enrofloxacin…100mg/100ml is mentioned; the firm has clarified that **Enrofloxacin…10Gm/ 100ml** is required.
	Decision: Approved with innovator's specifications. Registration letter shall be issued upon submission of fee of Rs.30,000/- for revision /pre-approval correction of label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
10.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Flor Plus Solution 25% w/v
	Composition	Each ml Contains: Florfenicol…25% w/v
	Diary No. Date of R& I & fee	Dy.No 13785 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per Innovator specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: As recommended by the PRC/(M/o NHS, R&C)/ Federal Govt.
	Me-too status	Florfenicol Oral Liquid of M/s ATTABAK Pharmaceuticals, Islamabad. (Reg. No. 075707)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	
	Decision: Approved	
11.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Enromizin Oral Liquid
	Composition	Each ml Contains: Enrofloxacin…75mg Sulphamethoxypyridazin…75mg Sulphamethazin…50mg Trimethoprim…25mg
	Diary No. Date of R& I & fee	Dy.No 13763 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: As recommended by the PRC/(M/o NHS, R&C)/ Federal Govt.
	Me-too status	Sinaset Oral Liquid of M/s Decent Pharma, Islamabad. (Reg. No. 095624)
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.

	Remarks of the Evaluator [X]	• Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for revision of finished product specifications.
	Decision: Approved with innovator's specifications. Registration letter shall be issued upon submission of fee of Rs.7500/- for revision/pre-approval correction of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
12.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km Chakbeli Road, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Vita CE Oral Liquid
	Composition	Each Litre Contains: Vitamin E Acetate…200000mg Vitamic C Ascorbic Acid…2000mg Sodium Selenite…2200mg Zinc As Sulphate…10000mg
	Diary No. Date of R& I & fee	Dy.No 13755 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml: As recommended by the PRC/(M/o NHS, R&C)/ Federal Govt.
	Me-too status	Could not be confirmed.
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator [X]	• Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Undertaking as per 251st meeting of Registration Board has not been signed by Production manager and Quality Control manager.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
13.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Respolex Oral Powder
	Composition	Each Gram Contains: Tylosin Tartrate…200mg Doxycycline HCl…400mg

	Diary No. Date of R& I & fee	Dy.No 16185 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	ETER-DOX WATER SOLUBLE POWDER Reg. No. 109 863
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Powder Section Veterinary** confirmed vide letter No. F. 2-4/99-Lic (Vol-II) dated 15-06-2021. • Tylosin Tartrate…200mg/gm and Doxycycline HCl…400mg/gm is mentioned throughout the dossier while Tylosin Tartrate…250mg/gm and Doxycycline HCl…200mg/gm is mentioned on cover letter; clarification is required for which strength you want to apply this dossier. • Full fee of registration for revision of quantities of APIs and inclusion of finished product specifications. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Master formulation describing quantities of actives and inactives alongwith their justification/role of ingredients. • Initially firm has applied for formulation containing Doxycycline HCl and now revised formulation in line with reference product as mentioned below: **Each 100Gram Contains:** **Tylosin tartrate ……20gm** **Doxycycline hyclate …...40gm**
	Decision: Approved with following label claim and with Innovator's Specifications: **Each 100gm contains:** **Tylosin tartrate ……20gm** **Doxycycline hyclate …...40gm** **Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
14.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Micotil Oral Liquid 250mg/ml
	Composition	Each ml Contains: Tilmicosin As Phosphate…250mg
	Diary No. Date of R& I & fee	Dy.No 16188 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	Micosil Oral Liquid of M/s Fizi Pharmaceuticals and Chemical Laboratories, Lahore.(Reg. No. 103830)

	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section Veterinary** confirmed panel inspection report dated 15-02-2021 for renewal of DML. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Full fee of registration for revision of master formula in terms of equivalency and adjustment of weight as per salt factor and inclusion of finished product specifications.
	Decision: Approved with following label claim and with innovator's specifications. **Each ml Contains:** **Tilmicosin Phosphate…250mg** **Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
15.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Broncolex Oral Liquid 50mg/ml
	Composition	Each ml Contains: Bromhexine (as HCl)…50mg
	Diary No. Date of R& I & fee	Dy.No 16189 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	BIOHEXIN 5% SOLUTION Reg. No. 103973.
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section Veterinary** confirmed panel inspection report dated 15-02-2021 for renewal of DML. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications.
	Decision: Approved with following label claim and with innovator's specifications. **Each ml Contains:** **Bromhexine HCl…50mg** **Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
16.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Enrocon Oral Liquid 20gm/4gm

	Composition	Each 100ml Contains: Enrofloxacin…20Gm Colistin Sulphate…4Gm
	Diary No. Date of R& I & fee	Dy.No 16186 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	Not provided
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section Veterinary** confirmed panel inspection report dated 15-02-2021 for renewal of DML. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
17.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Virakil Oral Powder 10gm
	Composition	Each 100Gm Contains: **Amantadine HCl…10Gm**
	Diary No. Date of R& I & fee	Dy.No 16182 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	Amandin Water Soluble Powder of M/s FIZI Pharmaceuticals and Chemical Laboratories, Lahore.(Reg. No. 103819)
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Powder Section Veterinary** confirmed vide letter No. F. 2-4/99-Lic (Vol-II) dated 15-06-2021. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.

		• Fee Rs. 7,500/- for inclusion of finished product specifications.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
18.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Neolex-P Oral Powder 72gm
	Composition	Each 100gm Contains: Neomycin Sulphate…72gm
	Diary No. Date of R& I & fee	Dy.No 16183 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	NEOSEL-72 ORAL POWDER Reg. No. 088098
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Powder Section Veterinary** confirmed vide letter No. F. 2-4/99-Lic (Vol-II) dated 15-06-2021. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications.
	Decision: Approved with innovator's specifications. Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
19.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Tybrox Oral Liquid
	Composition	Each ml Contains: Tylosin Tartrate…100mg Doxycycline Hyclate…200mg Colistin Sulphate…0.5 MIU Bromhexine…5mg
	Diary No. Date of R& I & fee	Dy.No 16190 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	RESPIDOX-T ORAL LIQUID Reg. No. 079120
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Powder Section Veterinary** confirmed vide letter No. F. 2-4/99-Lic (Vol-II) dated 15-06-2021. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is

		non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications. • Master formulation describing quantities of actives and inactives alongwith their justification/role of ingredients. • Provide conversion of Colistin Sulphate MIU to mg. • Firm has revised formulation as under: **Each ml Contains:** **Tylosin Tartrate…100mg** **Doxycycline HCl…200mg** **Colistin Sulphate…0.5 MIU** **Bromhexine……5mg**
	Decision: Approved with Innovator's Specification and with following label claim: **"Each ml Contains:** **Tylosin Tartrate…100mg** **Doxycycline HCl…200mg** **Colistin Sulphate…0.5 MIU** **Bromhexine……5mg"** **Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
20.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Fenlex Oral Liquid 23gm
	Composition	Each 100ml Contains: Florfenicol…23gm
	Diary No. Date of R& I & fee	Dy.No 16187 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	BAFLOR-23 ORAL SOLUTION. Reg. No. 071096
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	• Approval of **Powder Section Veterinary** confirmed vide letter No. F. 2-4/99-Lic (Vol-II) dated 15-06-2021. • Fee Rs. 7,500/- for inclusion of finished product specifications.
	Decision: Approved with innovator's specifications. Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
21.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals Pvt Ltd. 158-D, Tore, Gadap Road, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Lexi-Dox Oral Powder 500mg
	Composition	Each gram Contains: Doxycycline Hyclate…500mg
	Diary No. Date of R& I & fee	Dy.No 16184 dated 07-03-2019 Rs.20,000/- dated 07-03-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	As per SRO/As per SRO
	Me-too status	SELDOX POWDER Reg. No. 058717
	GMP status	Panel inspection report dated 15-02-2021 for renewal of DML.
	Remarks of the Evaluator [X]	Approval of **Powder Section Veterinary** confirmed vide letter No. F. 2-4/99-Lic (Vol-II) dated 15-06-2021.
	Decision: Approved with innovator's specifications. Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
22.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	Aro Mox Powder 200mg/10,00,000IU
	Composition	Each gm Contains: Amoxicillin…200mg Colistin Sulphate…10,00,000IU
	Diary No. Date of R& I & fee	Dy.No 16371 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Broad spectrum beta-lactam-polypeptide Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm,50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg: Decontrolled
	Me-too status	Colistin-Mox 200/1 Water Soluble Powder of M/s. Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113578)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	• Approval of **Dry Penicillin Powder Section Veterinary** confirmed vide letter No. F. 3-9/91-Lic (Vol-I) dated 21-06-2017. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise the master formula and/or label claim as per reference product for equivalency and adjustment of weight as per salt factor. • Full fee of Registration for revision of master formula and/or label claim as per reference product in terms of equivalency and adjustment of weight as per salt factor and inclusion of finished product specifications. • Provide conversion of Colistin Sulphate MIU to mg.
	Decision: Approved with following label claim and with innovator's specifications upto pack size 1Kg: **Each gm Contains:** **Amoxicillin as trihydrate…200mg** **Colistin Sulphate…10,00,000IU** **Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
23.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur

	Brand Name +Dosage Form + Strength	Gumbo Care Powder
	Composition	Each 100gm Contains: Potassium Citrate…18gm Sodium Citrate…12gm Vitamin B1…0.03gm Vitamin B2…0.015gm Nicotinamide…0.32gm Menadione Bisulfite…0.115gm Vitamin C…1.10gm
	Diary No. Date of R& I & fee	Dy.No 16370 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin preparation
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm,50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg: Decontrolled
	Me-too status	Anti Gumbo Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046581)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	• Approval of **Dry Penicillin Powder Section Veterinary** confirmed vide letter No. F. 3-9/91-Lic (Vol-I) dated 21-06-2017.
	Decision: Approved upto pack size of 1Kg.	
24.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	D-20 Powder
	Composition	Each 100gm powder contains: Doxycycline HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 16373 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm,50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg: Decontrolled
	Me-too status	NEODOX-20 POWDER Reg. No. 111427
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	• **Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. • Revise the master formula and/or label claim as per reference product for equivalency and adjustment of weight as per salt factor. • Full fee of Registration for revision of master formula and/or label claim as per reference product for equivalency and adjustment of weight as per salt factor.
	Decision: Approved upto pack size of 1Kg.	
25.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur

	Brand Name +Dosage Form + Strength	E-Line Liquid 10gm/4gm/10gm
	Composition	Each 100ml Contains: Enrofloxacin…10gm Aminophylline…4gm Guaifenesin…10gm
	Diary No. Date of R& I & fee	Dy.No 16369 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Tetracycline antibiotic, bronchodilator, expectorant
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter, 15Liter, 20Liter, 25Liter,: Decontrolled
	Me-too status	EG Enro Plus Liquid of M/S Elegance Pharmaceutical, Chak Belli, Rawalpindi (Reg. No. 074099)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved upto pack size of 1Litre.	
26.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	Fendox Liquid 20gm/10gm/8gm/20gm
	Composition	Each 100ml Contains: Doxycycline HCl…20gm Tylosin Tartrate…10gm Aminophylline…8gm Guaifenesin…20gm
	Diary No. Date of R& I & fee	Dy.No 16368 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Tetracycline antibiotic, bronchodilator, expectorant
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter, 15Liter, 20Liter, 25Liter,: Decontrolled
	Me-too status	TYCO-G ORAL LIQUID of M/s ATTABAK Pharmaceuticals, Islamabad. (Reg. No. 075704)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved upto pack size of 1Litre.	
27.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Napravin IMM Injector 3gm
	Composition	Each 3Gm Syringe Contains: Cefalonium As Dihydrate……250mg
	Diary No. Date of R& I & fee	Dy.No 16871 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial for intramammary use, cephalosporin
	Type of Form	Form 5

	Finished product Specification	BP specifications
	Pack size & Demanded Price	3gm/**injector tube**; Decontrolled
	Me-too status	Cepravin TM Dry Cow Intra Mammary of M/S ICI Pakistan Ltd Karachi (Reg. No. 020133) **(as SYRINGE)**
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	Approval of **Liquid injection section (veterinary) (Cephalosporin**) confirmed vide letter No.F. 2-10/93-Lic (Vol-I) dated 10-03-2022
	Decision: Approved	
28.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Nefa-Mac IMM Injector 10ml
	Composition	Each 10ml Syringe Contains: Cephalexin Monohydrate…200mg Neomycin Sulphate…340mg Cloxacillin Benzathine…500mg Vitamin A…10,000 IU
	Diary No. Date of R& I & fee	Dy.No 16872 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic infusion for dry cows
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Cefa sec of M/s Mustafa brothers. Reg No. 053956
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• Approval of **Liquid injection section (veterinary) (Cephalosporin)** confirmed vide letter No.F. 2-10/93-Lic (Vol-I) dated 10-03-2022. • Provided following conversion of vitamin A from IU to mg Potency of Vitamin A Palmitate per syringe = 6.25mg • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.
	Decision: Approved with innovator's Specifications and with following label claim: **"Each 10ml Syringe Contains:** **Cephalexin as Monohydrate…200mg** **Neomycin as Sulphate…340mg** **Cloxacillin Benzathine…500mg** **Vitamin A…10,000 IU"** • **Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
29.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	M-10 Powder
	Composition	Each gm Contains: Amoxicillin Base…100mg

		Colistin Sulphate…500,000 IU
	Diary No. Date of R& I & fee	Dy.No 16372 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Broad spectrum beta-lactam-polypeptide Antibiotic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	10gm, 20gm, 30gm,50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	• Approval of **Dry Penicillin Powder Section Veterinary** confirmed vide letter No. F. 3-9/91-Lic (Vol-I) dated 21-06-2017. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise the master formula and/or label claim as per reference product for equivalency and adjustment of weight as per salt factor. • Full fee of Registration for revision of master formula and/or label claim as per reference product in terms of equivalency and adjustment of weight as per salt factor and inclusion of finished product specifications. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide conversion of Colistin Sulphate MIU to mg. • Undertaking as per 251st meeting of Registration Board has not been provided on company's letterhead.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
30.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Peractin-T Injection 20mg/ml
	Composition	Each ml Contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 17318 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anthelmentic
	Type of Form	Form-5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	FLORAMEC Injection of M/s D-MAARSON PHARMACEUTICALS, ISLAMABAD (Reg. No. 078343)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Injection Section (Veterinary)** confirmed from Inspection report dated 11-05-2018 for renewal of DML

		• New suggested name: Ivoshell 20mg injection • Firm has revised finished product specification from in-house to "BP Vet specifications" along with the fee of Rs. 7,500/- via deposit slip no 4580995498.
	Decision: Approved with BP (Vet) specifications.	
31.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ivoshell 10mg Injection
	Composition	Each ml Contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 17315 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anthelmentic
	Type of Form	Form-5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	IVOBAK Injection of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 053908)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Injection Section (Veterinary)** confirmed from Inspection report dated 11-05-2018 for renewal of DML • Firm has revised finished product specification from in-house to "BP Vet specifications" along with the fee of Rs. 7,500/- via deposit slip no 30680664.
	Decision: Approved with BP (Vet) specifications.	
32.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ivoshell super Injection 10/100mg
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 17316 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anthelmentic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ivobak-C Injection of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 062156)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Injection Section (Veterinary)** confirmed from Inspection report dated 11-05-2018 for renewal of DML • Firm has revised finished product specification from in-house to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 08194455.
	Decision: Approved with innovator's specifications.	

33.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Dyrox N Powder
	Composition	Each 12gm Contains: Neomycin Sulphate…400mg Streptomycin Sulphate…400mg Sulfaguanidine…4gm Kaolin…4gm Pectin…400mg Bismuth Subnitrate…2gm Vitamin A Acetate…80,000IU
	Diary No. Date of R& I & fee	Dy.No 17317 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-bacterial, anti-diarrhoeal, Anti-infective
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	12gm, 60gm,100gm, 150gm, 250gm, 500gm, 1000gm, 2.5Kg; Decontrolled
	Me-too status	Diarrobak Water Soluble Powder of M/s Attabak Pharmaceuticals Islamabad. (Reg. No.063835)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Oral powder Section (Veterinary)** confirmed from Inspection report dated 11-05-2018 for renewal of DML. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 8636532536. • Moreover, the firm has provided following conversion of vitamin A acetate from IU to mcg. 1 IU= 0.3mcg of Vitamin A acetate.
	Decision: Approved with innovator's specifications.	
34.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Bromofloxin Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin…20gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy.No 16359 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/ anti-bacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5Liter; Decontrolled
	Me-too status	Rofl Liquid of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. no. 101976)
	GMP status	Last GMP inspection is conducted on 12-08-2022 and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** confirmed vide letter No.F. 1-36/2006-Lic (Vol-III) dated 29-09-2021.

		• Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 645001089019.
	Decision: Approved with innovator's specifications.	
35.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tilmobiotic Oral Solution
	Composition	Each ml Contains: Tilmicosin As Tilmicosin Phosphate…250mg
	Diary No. Date of R& I & fee	Dy.No 16361 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Me-too status	TIL MICO STER 25% Oral Liquid of M/s Aamster Laboratories, Islamabad.(Reg. No. 101427)
	GMP status	Last GMP inspection is conducted on **12-08-2022** and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** confirmed vide letter No.F. 1-36/2006-Lic (Vol-III) dated 29-09-2021. • Firm has revised finished product specification from in-house to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 26322561.
	Decision: Approved with innovator's specifications.	
36.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Floristin Oral Solution
	Composition	Each 100ml Contains: Florfenicol……23gm Colistin Sulphate…..50MIU
	Diary No. Date of R& I & fee	Dy.No 16360 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/ Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5Liter; Decontrolled
	Me-too status	Noaflotin Oral Solution of M/s. Noa Hemis Pharmaceuticals, Karachi. (Reg. No. 106679)
	GMP status	Last GMP inspection is conducted on **12-08-2022** and the report concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** confirmed vide letter No.F. 1-36/2006-Lic (Vol-III) dated 29-09-2021. • Firm has revised finished product specification from inhouse to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 54711720218. • Florfenicol…**23gm/100ml** was mentioned in label claim on Form-5 while Florfenicol…**23mg/100ml** was

		mentioned in master formula; upon clarification the firm has submitted revised master formula as per reference product. • Moreover, the firm has provided following conversion of Colistin Sulphate. 1mg of Colistin Sulphate = 19000 IU .
	Decision: Approved with following label claim: **"Each 100ml Contains:** **Florfenicol …… 23gm** **Colistin Sulphate ….. 50MIU"** **Registration letter shall be issued after submission of differential fee of Rs.22500/- for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
37.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries. L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reotilcon Solution 250mg/ml
	Composition	Each ml Contains: Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 16832 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/ Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Tilcosin-25 Oral Solution of M/s Nawan Lab Karachi (Reg. No. 058986)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 13235420.
	Decision: Approved with Innovator's Specifications.	
38.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reoflor C Solution
	Composition	Each 1000ml Contains: Florfenicol…230gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 16841 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/ Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Me-too status	C-Flor Oral Liquid of M/s Nawan Lab Karachi (Reg. No. 074782)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.

	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 77665259. • Provided conversion of Colistin sulphate from MIU to gm i.e. 1mg = 19000IU.
	Decision: Approved with Innovator's Specifications.	
39.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Derox 24% Liquid
	Composition	Each 100ml Contains: Enrofloxacin…10gm Aminophylline…4gm Guaifenesin…10gm
	Diary No. Date of R& I & fee	Dy.No 16830 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/ Expectorant
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	ANROX PLUS-10% ORAL LIQUID of M/s BIO-Labs (Pvt) Ltd., Islamabad (Reg. No. 033240)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 33535609598.
	Decision: Approved with Innovator's Specifications.	
40.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Deox-L Suspension
	Composition	Each 5ml Contains: Oxyclozanide…150mg Levamisole as HCl…75mg
	Diary No. Date of R& I & fee	Dy.No 16829 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	50ml, 100ml, 150ml, 500ml, 1Liter; Decontrolled
	Me-too status	SPECTRUM DRENCH of M/s Fizi Pharmaceuticals and Chemical Laboratories, Lahore. (Reg. No. 081331)

	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 504979836406.
	Decision: Approved with Innovator's Specifications with following label claim: **"Each 5ml Contains:** **Oxyclozanide…150mg** **Levamisole HCl…75mg"** **Firm shall submit differential fee of Rs.22500/- for correction in formulation , as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
41.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reoquintel Suspension
	Composition	Each 100ml Contains: Triclabendazole…12% w/v Levamisole…7.5% w/v
	Diary No. Date of R& I & fee	Dy.No 16833 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Prequintel Suspension of M/s Noble Pharma, Mirpur Azad Kashmir. (Reg. No. 063637)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Levamisole…7.5% w/v is mentioned in label claim on Form-5 while Levamisole **HCl**…7.5gm/100ml is mentioned in master formula; revise label claim and/or master formula as per reference product accordingly. • Full fee of registration for revision of master formula and/or label claim in terms of equivalency and adjustment of weight as per salt factor and inclusion of finished product specifications.
	Decision: Approved with Innovator's Specifications with following label claim: **"Each 100ml Contains:** **Triclabendazole……12% w/v** **Levamisole HCl……7.5% w/v"**	

	Firm shall submit fee of Rs.30000/- for correction in formulation , as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
42.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reotrime Oral suspension
	Composition	Each 200ml Contains: Sulphadiazine…80gm Trimethoprim…16gm Tylosin Tartrate…4gm
	Diary No. Date of R& I & fee	Dy.No 16838 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	50ml, 100ml, 200ml, 500ml, 1Liter; Decontrolled
	Me-too status	NOBI-TRIME SUSPENSION Reg. No. 058736
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Liquid Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications. • Firm has revised formulation as under: Each 200ml Contains: Sulphadiazine…80gm Trimethoprim…16gm Tylosin Tartrate…2gm
	Decision: Approved with Innovator's Specifications with following label claim: **"Each 200ml Contains:** **Sulphadiazine…80gm** **Trimethoprim…16gm** **Tylosin Tartrate…2gm"** **Firm shall submit fee of Rs.30000/- for correction in formulation , as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
43.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reodox-C Powder
	Composition	Each 1000gm Contains: Tylosin Tartarte…10% Doxycycline Hyclate…20% Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 16840 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg; Decontrolled

	Me-too status	CT-DOX WATER SOLUBLE POWDER Reg. No. 048172
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Provided conversion of Colistin sulphate from MIU to gm i.e. 1mg= 19000IU • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 75283657763.
	Decision: Approved with Innovator's Specifications.	
44.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reo DTCB Powder
	Composition	Each 1000gm Contains: Tylosin Tartrate…200gm Doxycycline HCl…400gm Colistin Sulphate…1000MIU Bromhexine…10gm
	Diary No. Date of R& I & fee	Dy.No 16839 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	50gm, 100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg; Decontrolled
	Me-too status	MONODOXWATER SOLUBLE POWDER Reg. No. 087142
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Full fee of Registration for revision of label claim and master formula and inclusion of finished product specifications. • Provided conversion of Colistin sulphate from MIU to gm i.e. 1mg = 19000IU • Revise label claim and master formula in terms of salt form of Bromhexine, in line with reference product and adjust its weight as per salt factor accordingly.
	Decision: Approved with Innovator's Specifications with following label claim: **Each 1000gm Contains:** **Tylosin Tartrate…200gm** **Doxycycline HCl…400gm** **Colistin Sulphate…1000MIU**	

	Bromhexine HCl…10gm • **Firm shall submit fee of Rs.30000/- for correction in formulation , as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
45.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Delxin-TD Powder
	Composition	Each 1000gm Contains: Tylosin Tartrate…10gm Doxycycline HCl…20gm Colistin Sulphate…480MIU Bromhexine…5gm
	Diary No. Date of R& I & fee	Dy.No 16831 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg; Decontrolled
	Me-too status	MAXDOXWATER SOLUBLE POWDER Reg. No. 087144
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Bromhexine…**5gm**/1000gm is mentioned in label claim on Form-5 while Bromhexine…**0.5gm**/1000gm is mentioned in master formula; revise label claim and/or master formula as per reference product accordingly. • Full fee of Registration for revision of label claim and master formula and inclusion of finished product specifications. • Provided conversion of Colistin sulphate from MIU to gm i.e 1mg = 19000IU
	Decision: Approved with Innovator's Specifications with following label claim: **"Each 1000gm Contains:** **Tylosin Tartrate…10gm** **Doxycycline HCl…20gm** **Colistin Sulphate…480MIU** **Bromhexine HCl…5gm"** **Firm shall submit fee of Rs.30000/- for correction in formulation , as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
46.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reo TDC 680 Powder
	Composition	Each 1000gm Contains: Tyloson Tartarte…200gm Doxycycline HCl…400gm Colistin Sulphate…60gm Bromhexine…20gm

	Diary No. Date of R& I & fee	Dy.No 16842 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg,5Kg; Decontrolled
	Me-too status	Nobi TDC 680 Powder of M/s Noble Pharma, Mirpur Azad Kashmir. (Reg. No. 062127)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 39253864474.
	Decision: Approved with Innovator's Specifications with following label claim: **Each 1000gm Contains:** **Tyloson Tartarte…200gm** **Doxycycline HCl…400gm** **Colistin Sulphate…60gm** **Bromhexine HCl…20gm** **Firm shall submit differential fee of Rs.22500/- for correction in formulation , as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
47.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reoneo 72% Powder
	Composition	Each 1000gm Contains: Neomycin Sulphate…720gm
	Diary No. Date of R& I & fee	Dy.No 16836 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg; Decontrolled
	Me-too status	NOBINEO oral Powder of M/s Noble Pharma, Mirpur Azad Kashmir. (Reg. No. 058726)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 5335178622.
	Decision: Approved with Innovator's Specifications	

48.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reo Asper C Powder
	Composition	Each 100gm Contains: Acetylsalicyclic Acid…6.70gm Vitamin C…20gm
	Diary No. Date of R& I & fee	Dy.No 16837 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antistress in action
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg; Decontrolled
	Me-too status	Gesix-C Water Soluble Powder of M/s PRIX Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 043286)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for inclusion of finished product specifications. • Undertaking as per 251st meeting of Registration Board has not been provided. **Shortcomings:** **Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
49.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reolincol Powder
	Composition	Each 1gm Contains: Lincomycin Sulphate…100mg Colistin Sulphate…800,000 IU
	Diary No. Date of R& I & fee	Dy.No 16834 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg; Decontrolled
	Me-too status	NOBI-LINCOL POWDER Reg. No. 079116
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.

		• Fee Rs. 7,500/- for inclusion of finished product specifications. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 0769239210.
	Decision: Approved with Innovator's Specifications	
50.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reoamant 10% Powder
	Composition	Each 100gm Contains: Amantadine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 16828 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Amandin Water Soluble Powder of M/s FIZI Pharmaceuticals and Chemical Laboratories, Lahore.(Reg. No. 103819)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.
	Remarks of the Evaluator [X]	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 8223318902.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
51.	Name and address of manufacturer / Applicant	M/s Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Reo CCNS Powder
	Composition	Each gm Contains: Chlortetracycline HCl…200mg Colistin Sulphate…10mg Neomycin Sulphate…60mg Streptomycin Sulphate…20mg
	Diary No. Date of R& I & fee	Dy.No 16835 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100gm, 500gm, 1000gm; Decontrolled
	Me-too status	Chlorocept Water Soluble Powder of M/s PRIX Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 073996)
	GMP status	Firm submitted DML renewal inspection report dated 09-06-2022.

	Remarks of the Evaluator [X]	• Approval of **Oral Powder Section (General) (veterinary)** is confirmed from DML renewal inspection. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Firm has submitted fee of Rs. 7,500/- for correction in specifications via deposit slip no 25458448996.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
52.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobidox C Powder
	Composition	Each 1000gm Contains: Tylosin Tartarte…10% Doxycycline Hyclate…20% Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 16594 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm,500gm, 1Kg and 5Kg jars; Decontrolled
	Me-too status	CT-DOX Water Soluble Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 048172)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• Approval of **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 • Firm has claimed inhouse specifications along with the fee of Rs. 7,500/- via deposit slip no 2011480749 for inclusion of finished product specification. • Moreover, the firm has submitted conversion of Colistin MIU to mg: 1mg=19000IU Now calculate it for 1000gm (1Kg) 1mg 19000IU X 500MIU (**1M IU= 100000IU)** X= **500,00000IU** x 1mg/ 19000IU X=2631.57mg X=2.631gm
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report by QA&LT Division.	
53.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobioxfen T Suspension

	Composition	Each 1000ml Contains: Oxfendazole…22.65gm Triclabendazole…85gm
	Diary No. Date of R& I & fee	Dy.No 16593 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anthelmintic/ De wormer
	Type of Form	Form 5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Triloxal Oral Suspension of M/s D-HAANS Pharmaceuticals, Azad Kashmir. (Reg. No. 102249)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• Approval of **Veterinary Oral Liquid (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 • Initially Oxfendazole…22.65 and Triclabendazole…85gm /1000ml was mentioned in label claim on Form-5 while Albendazole…10gm, Ivermectin 0.2gm and Triclabendazole…12gm/ 100ml was mentioned in master formula; upon clarification the firm has submitted the correct composition as mentioned below: **Each 1000ml Contains:** **Oxfendazole…22.65gm** **Triclabendazole…85gm** • Firm has claimed inhouse specifications along with the fee of Rs. 30,000/- via deposit slip no 56115640 for correction of formulation in label claim/ master formula.
	Decision: Approved with innovator's specifications with following label claim: **Each 1000ml Contains:** **Oxfendazole…22.65gm** **Triclabendazole…85gm** • **Registration letter will be issued after satisfactory GMP compliance report by QA&LT Division.**	
54.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Flukacure Suspension
	Composition	Each ml Contains: Fenbendazole…50mg Rafoxanide…50mg
	Diary No. Date of R& I & fee	Dy.No 16591 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anthelmintic/ De wormer
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	FEN FOXAMIDE LIQUID of M/s Leads Pharma Pvt. Ltd., Islamabad. (Reg. No.058837)

	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• Approval of **Veterinary Oral Liquid (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 • Firm has claimed inhouse specifications along with the fee of Rs. 7,500/- via deposit slip no 34095710 for inclusion of finished product specification.
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report by QA&LT Division.	
55.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobispiracin Injection
	Composition	Each ml contains: Spiramycin Adipate…125mg Lincomycin HCl…75mg
	Diary No. Date of R& I & fee	Dy.No 16590 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	**50ml,100ml**; Decontrolled
	Me-too status	I-Spiralink Injection of M/s International Pharma Labs, Lahore. (Reg. No. 062074)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• Approval of **Veterinary Liquid Vial Injection (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 • Firm has claimed inhouse specifications along with the fee of Rs. 7,500/- via deposit slip no 218112547 for inclusion of finished product specification. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report by QA&LT Division and selection of one fill volume.	
56.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobiket Injection
	Composition	Each ml contains: Ketoprofen…100mg

	Diary No. Date of R& I & fee	Dy.No 16592 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form 5
	Finished product Specification	BP Vet Specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Dinalgen Injection of M/s Mylab (Pvt) Ltd. Bahawalpur. (Reg. No. 074012)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• Approval of **Veterinary Liquid Vial Injection (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 • Firm has claimed BP Vet specifications **without submitting fee for inclusion of finished product specifications.**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
57.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Maxin Plus Injection
	Composition	Each ml Contains: Oxytetracycline (as dihydrate) …300mg Flunixin (as Maglumine)…20mg
	Diary No. Date of R& I & fee	Dy.No 430 dated 12-03-2019 Rs.20,000/- dated 11-03-2019
	Pharmacological Group	Antibacterial/Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	**Manufacturer's specifications**
	Pack size & Demanded Price	50ml; As per SRO
	Me-too status	Flunox Injection 300mg/ 20mg of M/s S.J & G Fazul Ellahie (Pvt.) Ltd, Karachi. (Reg. No. 093828)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • Firm has claimed **manufacturer's specifications** and the applied product is non-pharmacopoeial. • **Lignocain HCl** is included in list of ingredients mentioned in master formula while the same has not been reflected in label claim and outline of method of manufacture; upon clarification the firm has submitted that **"*Lignocain HCL included in master formulation as excipient and its role is local anesthetic to avoid the injection pain*".** • **However, Hexasol LA Solution for Injection (HPRA approved) does not contain Lignocain HCl.**
	Decision: Approved with innovator's specifications. Firm shall submit correct master formulation excluding Lignocaine HCl in line with reference product before issuance of	

	registration letter with submission of Rs.30000/- fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
58.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Bromoras M Oral Liquid
	Composition	Each 1ml Contains: Bromhexine HCl…20mg Menthol……..40mg
	Diary No. Date of R& I & fee	Dy.No 1671 dated 25-03-2019 Rs.20,000/- dated 25-03-2019
	Pharmacological Group	Mucolytic/Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1Liter, 5Liter, 25Liter; N/A
	Me-too status	Bromo-Plus Liquid of M/s Elegance Pharmaceutical, Rawalpindi. (Reg. No.073917)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 76654590792.
	Decision: Approved with innovator's specification upto pack size of 1Litre.Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
59.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Methenasol-C Oral Powder
	Composition	Each 100gm Contains: Methenamine …90gm Vitamin B1……700mg Vitamin C……..100mg Sorbitol……..…5gm
	Diary No. Date of R& I & fee	Dy.No 1670 dated 25-03-2019 Rs.20,000/- dated 25-03-2019
	Pharmacological Group	Anti-infective Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 15gm, 25gm, 50gm, 100gm, 250gm, 500gm,1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; N/A
	Me-too status	A-Flush Water Soluble Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 049708)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Powder (General) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 7506281702.

	Decision: Approved with innovator's specifications upto pack size of 1Kg. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
60.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Promectin Alpha Injection 10ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 4260 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Endectocide, anthelmintic Flukicide
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml vial; Decontrolled
	Me-too status	Ivorok-Plus Injection of M/s Manhattan Pharma Karachi (Reg. No. 052368)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• Liquid Injectable (SVP) Vet section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017. • Firm has revised finished product specification to "**USP specifications"** along with the fee of Rs. 7,500/- via deposit slip no 8344981661.
	Decision: Approved with USP specifications.	
61.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Promectin Alpha Injection 50ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 4261 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Endectocide, anthelmintic Flukicide
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml vial; Decontrolled
	Me-too status	JFMEC-Super Injection of M/s Jfrin Pharmaceuticals, Hub Industrial Estate Balochistan. (Reg. No. 041211).
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• Liquid Injectable (SVP) Vet section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017 • Firm has revised finished product specification to **"USP specifications**" along with the fee of Rs. 7,500/- via deposit slip no 65612724.
	Decision: Approved with USP specifications.	
62.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Promectin Alpha Injection 100ml
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 4262 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Endectocide, anthelmintic Flukicide

	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml vial; Decontrolled
	Me-too status	JFMEC-Super Injection of M/s Jfrin Pharmaceuticals, Hub Industrial Estate Balochistan. (Reg. No. 041211).
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• Liquid Injectable (SVP) Vet section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017. • Firm has revised finished product specification to **"USP specifications"** along with the fee of Rs. 7,500/- via deposit slip no 5244164795.
	Decision: Approved with USP specifications.	
63.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Promectin Injection 10ml
	Composition	Each ml Contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 4257 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	10ml vial; Decontrolled
	Me-too status	Pandex 1% Injectable Solution of M/s Khyber Poultry Faisalabad. (Reg. No. 018859)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• Liquid Injectable (SVP) Vet section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017 • Firm has revised finished product specification to "**BP Vet specifications**" along with the fee of Rs. 7,500/- via deposit slip no 63930464044.
	Decision: Approved with BP Vet specifications.	
64.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Promectin Injection 50ml
	Composition	Each ml Contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 4258 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	50ml vial; Decontrolled
	Me-too status	Pandex 1% Injectable Solution of M/s Khyber Poultry Faisalabad. (Reg. No. 018859)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020. ▪ Liquid Injectable (SVP) Vet section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017
	Remarks of the Evaluator [X]	The firm has **withdrawn application** vide their letter No. nil dated 11-10-2022
	Decision: Registration Board acceded to the firm's request and declared the application as disposed of/rejected.	

65.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Promectin Injection 100ml
	Composition	Each ml Contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 4259 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	100ml vial; Decontrolled
	Me-too status	Avimec Injection of M/s U.M. Enterprises Karachi. (Reg. No. 019031)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020. Liquid Injectable (SVP) Vet section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017
	Remarks of the Evaluator [X]	The firm has **withdrawn application** vide their letter No. nil dated 11-10-2022
	Decision: Registration Board acceded to the firm's request and declared the application as disposed of/rejected.	
66.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Multimix Injection 50ml
	Composition	Each ml Contains: Vitamin A (palmitate)…15,000IU Vitamin D3……1,000IU Vitamin E (acetate) ...…20mg Vitamin B1 (HCl) …...…10mg Vitamin B2 (Riboflavin 5-Phosphate Sodium) …5mg Vitamin B6…3mg Nicotinamide…35mg D-Pantothenol…25mg Vitamin B12…5mcg
	Diary No. Date of R& I & fee	Dy.No 4255 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml vial; Decontrolled
	Me-too status	Multina injection of M/s Nawan laboratories. (Reg. No. 049512)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Vet** section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017 • Firm has revised finished product specification to "**as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 1711081231 • Provided conversion of Vitamin A and Vitamin D3 from IU to mg. VITAMIN A (Palmitate) BP .. 15,000 IU (8.82mg) (Vitamin A is equivalent to 1700IU/mg) VITAMIN D3 BP….. 1,000 IU (25mcg)

		(Vitamin D is equivalent to 40,000 IU/mg)
	Decision: Deferred for clarification regarding inclusion of both oil and water soluble vitamins in same formulation of injection dosage form.	
67.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Multimix Injection 100ml
	Composition	Each ml Contains: Vitamin A (palmitate)…15,000IU Vitamin D3……1,000IU Vitamin E (acetate) ...…20mg Vitamin B1 (HCl) …...…10mg Vitamin B2 (Riboflavin 5-Phosphate Sodium) …5mg Vitamin B6…3mg Nicotinamide…35mg D-Pantothenol…25mg Vitamin B12…5mcg
	Diary No. Date of R& I & fee	Dy.No 4256 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml vial; Decontrolled
	Me-too status	Multina injection of M/s Nawan laboratories. (Reg. No. 049512)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Liquid Injectable (SVP) Vet** section granted vide letter No. F.1-41/2007-Lic-(Vol-I) dated 10-07-2017 • Firm has revised finished product specification to "**As per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 94836692974. • Provided conversion of Vitamin A and Vitamin D3 from IU to mg. VITAMIN A (Palmitate) BP .. 15,000 IU (8.82mg) (Vitamin A is equivalent to 1700IU/mg) VITAMIN D3 BP….. 1,000 IU (25mcg) (Vitamin D is equivalent to 40,000 IU/mg)
	Decision: Deferred for clarification regarding inclusion of both oil and water soluble vitamins in same formulation of injection dosage form.	
68.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Triclev Plus Drench 120mg/75mg
	Composition	Each ml Contains: Triclabendazole…120mg Levamisole HCl…75mg
	Diary No. Date of R& I & fee	Dy.No 4253 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml and 1000ml; Decontrolled
	Me-too status	Endo Shell Liquid of M/S. Inshal Pharmaceutical Industries, Islamabad. (Reg. No.103929)

	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• Veterinary Oral Liquid (General) section granted vide letter No. F.1-41/2007-Lic dated 06-04-2015 • Firm has revised finished product specification to "**As per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 2812380379.
	Decision: Approved with innovator's specification.	
69.	Name and address of manufacturer / Applicant	M/s ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Zolectin Drench
	Composition	Each 100ml contains: Triclabendazole…12gm Ivermectin…….0.2gm Albendazole……...10gm
	Diary No. Date of R& I & fee	Dy.No 4254 dated 22-04-2019 Rs.20,000/- dated 19-04-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml and 1000ml; Decontrolled
	Me-too status	Thunder Drench of M/s Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058941)
	GMP status	cGMP certificate dated 30-03-2021 based on inspection conducted on 10-11-2020.
	Remarks of the Evaluator [X]	• **Veterinary Oral Liquid (General)** section granted vide letter No. F.1-41/2007-Lic dated 06-04-2015 • Firm has revised finished product specification to "**As per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 18724595074.
	Decision: Approved with innovator's specification.	
70.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Elyso WS Powder
	Composition	Each gram contains: Lysozyme…22% Vitamin E 50…0.5%
	Diary No. Date of R& I & fee	Dy.No 2497 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Nutritional supplement
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg and 25Kg; Decontrolled
	Me-too status	LISO 10 Powder of M/s Mallard Pharmaceutical (Pvt) Ltd., Multan (Reg. No. 049566)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 49400153.

	Decision: Deferred for following clarification: • **Rationale of Lysozyme and vitamin E formulation.** • **Evidence of approval status of applied formulation as drug product in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
71.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Mentholy Liquid
	Composition	Each Litre Contains: Peppermint…40gm Eucalyptus Oil…50gm Menthol…50gm Vitamin A…30,000,000IU
	Diary No. Date of R& I & fee	Dy.No 2496 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Decongestant
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter, and 5Liter; Decontrolled
	Me-too status	Fenetime Oral Solution of M/S Biogen Pharma, Rawat. (Reg. No. 063815)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 9549820869. • Firm has submitted following conversion of Vitamin A from IU to Kg 30,000,000 IU= 17.64gm 1700000 IU per gram
	Decision: Referred to committee for review of formulation in grey area as product contains ingredients regulated as H&OTC product.	
72.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Lincopharm 11 premix
	Composition	Each gram contains: Lincomycin as HCl…1.1%
	Diary No. Date of R& I & fee	Dy.No 2502 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg and 10Kg; Decontrolled
	Me-too status	Bio-Mycin 11% Premix Powder of M/s Bio-Labs (Pvt) Ltd, Islamabad. (Reg. No. 103971)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Powder Section (Antibiotic)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007.

		• Firm has revised finished product specification from inhouse to **"BP Vet specifications"** • The firm has submitted fee of Rs. 30,000/- via deposit slip no 379582668 for revision of label claim/master formula in terms of salt form, and finished product specifications.
	Decision: Approved with BP Vet Specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
73.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Paraflor Liquid 250gm/200gm
	Composition	Each 1000ml contains: Florfenicol…250gm Paracetamol…200gm
	Diary No. Date of R& I & fee	Dy.No 2492 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Antibacterial, antipyretic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter, and 5Liter; Decontrolled
	Me-too status	**Could not be confirmed from the available database**
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section** confirmed vide letter No. F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from in-house to "**as per innovator's specifications**" • Initially Paracetamol…**200mg/Liter** is mentioned in label claim on Form-5 while Paracetamol… .....**40Kg/200Liter** is mentioned in master formula; upon clarification the firm has submitted the correct formulation as below: **Each 1000ml contains:** **Florfenicol…250gm** **Paracetamol…200gm** • The firm has provided fee of Rs. 30,000/- via deposit slip no 436683344 for revision of finished product specification and correction of strength of API in label claim/ master formula. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm could not be verified.
	Decision: Deferred for following: • **Eevidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Review of applied formulation by Expert Working Group**	
74.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Tilmisol Liquid
	Composition	Each ml Contains: Tilmicosin as phosphate…250mg

	Diary No. Date of R& I & fee	Dy. No 2500 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter, and 5Liter; Decontrolled
	Me-too status	Til Mico Ster 25% Oral Liquid of M/s Aamster Laboratories, Islamabad. (Reg. No. 101427)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from USP to "**as per innovator's specifications"** • The firm has provided fee of Rs. 30,000/- via deposit slip no 7293907979 for revision of finished product specification and revision of label claim in terms of salt form in line with reference product.
	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
75.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Spectin Powder
	Composition	Each gram contains: Lincomycin as HCl…33.3% Spectinomycin Sulphate…66.7%
	Diary No. Date of R& I & fee	Dy.No 2501 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Lincotin Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049618)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Powder Section (Antibiotic)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**". • The firm has provided fee of Rs. 30,000/- via deposit slip no 75908383450 for revision of finished product specification and revision of label claim in terms of salt form in line with reference product. • The firm has applied for Lincomycin as HCl…33.3% and **Spectinomycin Sulphate…66.7%/gram**, while the referred generic product contains Lincomycin as HCl…33.3% and **Spectinomycin as Sulphate…66.7%/gram**. Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm; or revise formulation in line with reference product.
	Decision: Approved with innovator's specifications and with following label claim:	

	Each gram contains: **Lincomycin as HCl…….33.3%** **Spectinomycin as Sulphate…66.7%** **Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.**	
76.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Se Amoxylin 80% Powder
	Composition	Each 100gm Contains: Amoxicillin as trihydrate…80gm
	Diary No. Date of R& I & fee	Dy.No 2494 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Dokamox 80% Water Soluble Powder of M/S. Orient Animal Health (Pvt.) Limited, Karachi. (Reg. No. 082505)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Dry Powder Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017. • Firm has revised finished product specification from inhouse to "**BP Vet specifications**". • The firm has provided fee of Rs. 30,000/- via deposit slip no 71999083826 for revision of finished product specification and revision of label claim in terms of salt form in line with reference product.
	Decision: Approved with BP (Vet) specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
77.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Liver Up Liquid
	Composition	Each 100ml Contains: L Carnitine…5% Magnesium Sulphate…1% Sorbitol…20% Choline Chloride…10% Betain…2% Inositol…0.7%
	Diary No. Date of R& I & fee	Dy.No 2493 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Liver supplement
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, and 5Liter; Decontrolled
	Me-too status	Le Vox Liquid of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 081720)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007.

		• Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 30326971.
	Decision: Approved with innovator's specifications and change of brand name. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
78.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Fancy Flor Liquid 20gm
	Composition	Each 100ml Contains: Florfenicol…20gm
	Diary No. Date of R& I & fee	Dy.No 2498 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500ml, 1Liter, and 5Liter; Decontrolled
	Me-too status	Florfen-20% Oral Liquid of M/s Nawal Pharmaceuticals, Rawalpindi. (Reg. No. 074091)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 1181343038.
	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
79.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	LE-Bro Liquid 20mg/40mg
	Composition	Each ml Contains: Bromhexine HCl…20mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 2495 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter, and 5Liter; Decontrolled
	Me-too status	Menbro (Vet) Liquid of M/s Biorific Pharma, Islamabad. (Reg. No. 083827)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Liquid Section** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 28217337092.

	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
80.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Cylic Vit Powder
	Composition	Each 1000gm Contains: Acetyl Salicylic Acid…67gm Vitamin C…200gm
	Diary No. Date of R& I & fee	Dy.No 4870 dated 30-04-2019 Rs.20,000/- dated 30-04-2019
	Pharmacological Group	Restorative
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500gm, and 1Kg, 2.5Kg and 5Kg; Decontrolled
	Me-too status	Sali-C Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043537)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 088127575. **Shortcomings:** • **Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C is required.**
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
81.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Digesta Powder
	Composition	Each 1000gm Contains: Propionic Acid Calcium...250gm Propionic Acid Sodium…400gm Acetanilide…150gm Magnesium Oxide…125gm Iron II Sulphate…400mg Zinc Sulphate…100mg Magnesium Sulphate…200mg Copper Sulphate…450mg Cobalt Sulphate…400mg Sodium Molybdate…100mg Sodium Chloride…20gm
	Diary No. Date of R& I & fee	Form-5 Dy.No 4869 dated 30-04-2019 Rs.20,000/- dated 30-04-2019
	Pharmacological Group	Appetizing and digestive tonic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg and 25Kg; Decontrolled
	Me-too status	Could not be verified
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.

	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 3291337165. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.	
82.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Lincopharm 15% powder
	Composition	Each gram contains: Lincomycin as HCl…15%
	Diary No. Date of R& I & fee	Dy.No 4872 dated 30-04-2019 Rs.20,000/- dated 30-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, and 5Kg; Decontrolled
	Me-too status	Lincomicina 150 Ganadexil Oral Powder of M/s Forward Solutions, Lahore. (Reg. No. 078290)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Powder Section (Antibiotic)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. • Firm has revised finished product specification from inhouse to "**USP specifications**". • The firm has provided fee of Rs. 30,000/- via deposit slip no 605072970 for revision of finished product specification and revision of label claim in terms of salt form in line with reference product.
	Decision: Approved with USP specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
83.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Trepcin Powder
	Composition	Each 1000gm Contains: Amoxicillin as Trihydrate…100gm Colistin Sulphate…50gm Neomycin Sulphate…200gm
	Diary No. Date of R& I & fee	Dy.No 2499 dated 03-04-2019 Rs.20,000/- dated 02-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, and 5Kg; Decontrolled
	Me-too status	Neo AC Water Soluble Powder of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 079844)

	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Dry Powder Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 59440054000.
	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
84.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Ampileads Injection 200mg/ml
	Composition	Each ml suspension contains: Ampicillin trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 4587 dated 26-04-2019 Rs.20,000/- dated 25-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ampicillin 20% Injection of M/s Nawan Trading Corp. Karachi. (Reg. No. 014527)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Liquid Injection Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 95932742.
	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
85.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Lemoxil 15% Injection
	Composition	Each ml Contains: Amoxicillin Trihydrate eq to Amoxicillin Base…150mg
	Diary No. Date of R& I & fee	Dy.No 4586 dated 26-04-2019 Rs.20,000/- dated 25-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Almox 15% LA of M/s Star Labs Lahore. (Reg. No. 020842)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Liquid Injection Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017.

		• Firm has revised finished product specification from inhouse to "BP Vet specifications" along with the fee of Rs. 7,500/- via deposit slip no 9054367400.
	Decision: Approved with BP (Vet) specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
86.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Ledomentan Injection 140mg/35mg
	Composition	Each ml Contains: Amoxicillin Trihydrate…140mg Clavulanic Acid as Potassium Clavulanate…35mg
	Diary No. Date of R& I & fee	Dy.No 4588 dated 26-04-2019 Rs.20,000/- dated 25-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Nugmentan Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 072675)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Liquid Injection Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017. • Firm has revised finished product specification from inhouse to "As per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 8424591224.
	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
87.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Combipen Injection
	Composition	Each ml Contains: Benzathine Penicillin G…100,000IU Procain Penicillin…150,000IU Dihydrostreptomycin Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 4589 dated 26-04-2019 Rs.20,000/- dated 25-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Liquid Injection Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017. • Firm has revised finished product specification from inhouse to "As per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 89895916. • Provided conversion of Benzathine Penicillin G and Procain Penicillin from IU to kg as mentioned below: Benzathine Penicillin G 100,00 IU= 81mg

		Procain Penicillin 150,000 IU= 150mg • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.	
88.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Amcocin Injection
	Composition	Each ml Contains: Amoxicillin Trihydrate…100mg Colistin Sulphate…250,000IU
	Diary No. Date of R& I & fee	Dy.No 4585 dated 26-04-2019 Rs.20,000/- dated 25-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Penicillin Liquid Injection Section (Veterinary)** confirmed vide letter No.F. 1-34/2013-Lic dated 11-04-2017. • Firm has revised finished product specification from inhouse to "As per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 6269502340. • Provided conversion of Colistin sulphate from IU to kg as mentioned below: Colistin Sulphate 250,000 IU = 13.15mg **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required.	
89.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad.
	Brand Name +Dosage Form + Strength	Marboxin 100 injection
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 4871 dated 30-04-2019 Rs.20,000/- dated 30-04-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Marcin Injection (50ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 088117)

	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022.
	Remarks of the Evaluator [X]	• Approval of **Liquid Injection Section (General-Veterinary)** confirmed vide panel inspection report dated 29-11-18 and 01-01-2019, for issuance of gmp certificate. • Firm has revised finished product specification from inhouse to "as per innovator's specifications". • The firm has provided fee of Rs. 30,000/- via deposit slip no 362121782530 for revision of finished product specification and revision of master formula without overage.
	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
90.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Seldox Fort Powder
	Composition	Each gram contains: Doxycycline Hyclate eq to Doxycycline…800mg
	Diary No. Date of R& I & fee	Dy.No 4497 dated 25-04-2019 Rs.20,000/- dated 24-04-2019
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, and 1Kg; Decontrolled
	Me-too status	Doxyral 80% Water Soluble Powder of M/s Orient Animal Health (Pvt.) Limited, Karachi. (Reg. No. 082504)
	GMP status	Panel inspection dated 14-03-2022 for grant of additional Sections recommends grant of following additional sections Liquid injectable Cephalosporin (Vet) Dry Powder Injectable Cephalosporin (Vet) Liquid injectable Vial-I General (Vet) Liquid injectable vial-II General (Vet) External Liquid Preparation (Vet) External Powder Preparation (Vet)
	Remarks of the Evaluator [X]	• Oral powder (Veterinary) section confirmed vide letter No.F.1-13/2000-Lic (Vol-II) dated 23-01-2019 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 3833468637.
	Decision: Approved with innovator's specifications. Firm shall submit GMP inspection report conducted within last three years before issuance of registration letter.	
91.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Ever Gold Powder
	Composition	Each 1000 gm contains: Vitamin A...0.8gm Vitamin D3...0.16gm Vitamin E...0.38gm Vitamin B1...1 gm Vitamin B2...1.25 gm Vitamin B12...0.001 gm Vitamin B3...6.25 gm Copper Sulphate...0.25 gm Magnesium Sulphate...25 gm

		Calcium Chloride...0.023 gm Zinc Sulphate...2.17 gm Manganese Sulphate...10 gm Potassium Iodide...0.5 gm Sodium Selenite...0.01 gm Dicalcium Phospate...150 gm Sodium Chloride...120 gm Vitamin B6...4 gm
	Diary No. Date of R& I & fee	Dy.No 3631 dated 15-04-2019 Rs.20,000/- dated 15-04-2019
	Pharmacological Group	Vitamins with minerals
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, and 5Kg; Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No. 058842)
	GMP status	cGMP certificate dated 08-12-2021 based on inspection conducted on 07-12-2021.
	Remarks of the Evaluator [X]	• Approval of **Dry Powder Suspension (General) (veterinary)** section confirmed vide letter No.F. 1-31/2010-Lic dated 25-11-2016 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 0290350843.
	Decision: Approved with innovator's specifications and change of brand name.	
92.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Siahanwala, Faisalabad
	Brand Name +Dosage Form + Strength	Maji Enro-C 10 Oral Liquid
	Composition	Each 1000ml contains: Enrofloxacin…100gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 5674 dated 09-05-2019 Rs.20,000/- dated 09-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter and 5Liters; Decontrolled
	Me-too status	Encohil Oral Liquid of M/s. Hilton Pharma (Pvt.) Ltd., Karachi. (Reg. No.103943)
	GMP status	Panel inspection report for grant of DML based on inspection dated 17-10-2017 recommends the grant of DML
	Remarks of the Evaluator [X]	• **Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 3590933586. • Provided following conversion of Colistin Sulphate from MIU to gm. 19000 IU =1mg
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report conducted within last 3 years by QA&LT Division.	
93.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Siahanwala, Faisalabad

	Brand Name +Dosage Form + Strength	Maji Flor-C Oral Liquid
	Composition	Each 100ml Contains: Florfenicol…23gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 5677 dated 09-05-2019 Rs.20,000/- dated 09-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter and 5Liters; Decontrolled
	Me-too status	Fenicol Liquid of M/s. Univet Pharmaceuticals, Rawalpindi. (Reg. No. 079134)
	GMP status	Panel inspection report for grant of DML based on inspection dated 17-10-2017 recommends the grant of DML
	Remarks of the Evaluator [X]	• **Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 20168845. • Provided following conversion of Colistin Sulphate from MIU to gm. 19000 IU =1mg
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report conducted within last 3 years by QA&LT Division.	
94.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Siahanwala, Faisalabad
	Brand Name +Dosage Form + Strength	Maji Flor 25 Oral Liquid
	Composition	Each ml Contains: Florfenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 5676 dated 09-05-2019 Rs.20,000/- dated 09-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Liter and 5Liters; Decontrolled
	Me-too status	Lofen Oral Liquid of M/s. Inshal Pharmaceutical Industries, Islamabad (Reg. No. 103841)
	GMP status	Panel inspection report for grant of DML based on inspection dated 17-10-2017 recommends the grant of DML
	Remarks of the Evaluator [X]	• **Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 92634356.
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report conducted within last 3 years by QA&LT Division.	
95.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Siahanwala, Faisalabad
	Brand Name +Dosage Form + Strength	Maji Tylo-D40 Oral WSP

	Composition	Each 1000gm Contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm Bromhexine HCl…05gm
	Diary No. Date of R& I & fee	Dy.No 5675 dated 09-05-2019 Rs.20,000/- dated 09-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg and 25kg; Decontrolled
	Me-too status	Tb-Dox Powder of M/s. Attabak Pharmaceuticals, Islamabad. (Reg. No. 075718)
	GMP status	Panel inspection report for grant of DML based on inspection dated 17-10-2017 recommends the grant of DML
	Remarks of the Evaluator [X]	• **Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 • Firm has revised finished product specification from inhouse to **"as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 591695159.
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report conducted within last 3 years by QA&LT Division.	
96.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Siahanwala, Faisalabad
	Brand Name +Dosage Form + Strength	Maji Flox Oral Water Soluble Powder
	Composition	Each gram contains: Florfenicol…150mg Oxytetracycline HCl…150mg
	Diary No. Date of R& I & fee	Dy.No 5678 dated 09-05-2019 Rs.20,000/- dated 09-05-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	As Per Innovator's Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg and 25kg; Decontrolled
	Me-too status	Floxybar 30 Water Soluble Powder of M/s. Baariq Pharmaceuticals, Lahore. (Reg. No. 072601)
	GMP status	Panel inspection report for grant of DML based on inspection dated 17-10-2017 recommends the grant of DML
	Remarks of the Evaluator [X]	• **Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 817315860
	Decision: Approved with innovator's specifications. Registration letter will be issued after satisfactory GMP compliance report conducted within last 3 years by QA&LT Division.	
97.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Amolinc Water Soluble Powder
	Composition	Each 100gm contains: Lincomycin…8.8gm Spectinomycin…8.8gm Amoxicillin …20gm

	Diary No. Date of R& I & fee	Dy.No 6486 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator"s specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Amoxpeclin Oral Powder of M/s Selmore. (Reg. No. 102086)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	Initially, the firm has applied for Lincomycin…8.8gm Spectinomycin…8.8gm Amoxicillin …20gm per 100gram, Now the firm has revised formulation as mentioned below: **Each 100gm contains:** **Lincomycin HCl…8.8gm** **Spectinomycin dihydrochloride…8.8gm** **Amoxicillin trihydrate …20gm** • Full fee of registration vide slip no. **58064003778** for revision of label claim/ master formula, and finished product specifications. • Approval of **"Penicillin Oral powder (veterinary)"** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility is required.
	Decision: Deferred for evidence of Penicillin Oral powder (veterinary) section.	
98.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Amantacin Water Soluble Powder
	Composition	Each 100gm Contains: Enrofloxacin…10gm Colistin…3.5gm Amantadine…4gm
	Diary No. Date of R& I & fee	Dy.No 6491 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Antibacterial/anti-viral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Enflox Plus Powder, Reg. No. 052344.
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Firm has submitted approval of **Oral Dry Powder Suspension (veterinary) Section.** • Firm has revised spec to "**As per Innovator's Specifications**" • Firm has revised formulation as per reference with submission of full fee vide challan No. 0379985438 as **Each 100gm Contains:** **Enrofloxacin…10gm** **Colistin sulphate…3.5gm** **Amantadine HCl…4gm**

		Rationale of amantadine with antibiotics formulation
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
99.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Tydox Water Soluble Powder
	Composition	Each Kg contains: Tylosin Tartrate…100gm Doxycycline Hyclate…210gm
	Diary No. Date of R& I & fee	Dy.No 6488 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	DOXIN W/S POWDER, Reg. No. 017908
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Firm has submitted approval of **Oral Dry Powder Suspension (veterinary) Section.** • Firm has revised spec to "**As per Innovator's Specifications**" • Firm has revised formulation as per reference with submission of fee of rs. 30,000/- vide challan No. 54849919984 as **Each gram contains:** **Tylosin Tartrate…100mg** **Doxycycline HCl…200mg**
	Decision: Approved with innovator's specifications as per following label claim: **"Each gram contains:** **Tylosin Tartrate…100mg** **Doxycycline HCl…200mg"**	
100.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Levapoul water Soluble Powder
	Composition	Each 100gm contains: Levamisole HCl…15% w/w
	Diary No. Date of R& I & fee	Dy.No 6485 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Lemisole Powder of M/s Symans Pharmaceuticals, Lahore. (Reg. No. 013686)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of **Oral powder sachet (General/Antibiotic) (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • Firm has revised finished product specification from inhouse to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 95642091693.

	Decision: Approved with innovator's specifications.	
101.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Mandin Water Soluble Powder
	Composition	Each 1000gm contains: Amantadine HCl…980gm
	Diary No. Date of R& I & fee	Dy.No 6490 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Dopaminergic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Hansredin 98% Powder of M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber, Azad Kashmir. (Reg. No. 102207)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of **Oral powder sachet (General/Antibiotic) (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 1992629762.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
102.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Bronchez Water Soluble Powder
	Composition	Each 100gm of Powder Contains: Tylosin Tartrate…10gm Doxycycline Hyclate…20gm Colistin Sulphate…3gm Bromhexine HCl…1gm
	Diary No. Date of R& I & fee	Dy.No 6487 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Confirm salt form and equivalency factor as per reference product
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder/ Sachet (General/Antibiotic) Veterinary Section** confirmed from panel inspection report for renewal of DML verifying the section/manufacturing facility. • Firm has submitted approval of **Oral Dry Powder Suspension (veterinary) Section.** • Firm has revised spec to "**As per Innovator's Specifications**"

		• Firm has revised formulation as per reference with submission of fee of Rs. 30,000/- vide challan No.598581354 as **Each Kg Contains:** **Tylosin Tartrate…100gm** **Doxycycline HCl…200gm** **Colistin Sulphate…500MIU** **Bromhexine HCl…10gm**
	Decision: Approved with innovator's specifications as per following label claim: **"Each Kg Contains:** **Tylosin Tartrate…100gm** **Doxycycline HCl…200gm** **Colistin Sulphate…500MIU** **Bromhexine HCl…10gm"**	
103.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Febrol Injection 50ml
	Composition	Each ml Contains: Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 7567 dated 29-05-2019 Rs.20,000/- dated 27-05-2019
	Pharmacological Group	NSAID/Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 50ml vial; As per SRO
	Me-too status	Vetafenac-Super Injection of M/s S.J. & G. Fazul Ellahie (Pvt) Limited, Karachi. (Reg. No. 046569)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 4746891203.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
104.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Uriflo Water Soluble Powder
	Composition	Each 1000gm Contains: Sodium Chloride…35gm Magnesium Sulphate…35gm Potassium Chloride…400mg Furosemide…20gm Calcium Carbonate…40gm
	Diary No. Date of R& I & fee	Dy.No 6489 dated 20-05-2019 Rs.20,000/- dated 17-05-2019
	Pharmacological Group	Diuretic with electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled

	Me-too status	Neyphralyte Powder of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No.071072)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• **Oral powder Sachet (General/Antibiotic) (veterinary)** section confirmed by the panel inspection dated 14-12-2015 report for renewal of DML. • Initially the firm has applied for Sodium Chloride…35gm Magnesium Sulphate…35gm Potassium Chloride…400mg Furosemide…20gm Calcium Carbonate…40gm/1000gm, now revised the formulation in light with reference product as mentioned below: **Each 1000gm contains:** **Sodium Chloride…35gm** **Magnesium Sulphate…35gm** **Potassium Chloride…400mg** **Furosemide…20gm** **Calcium Carbonate…45gm** • Full fee of registration for revision of label claim/ master formula, and finished product specifications. Vide slip no. 266932344829
	Decision: Approved with innovator's specifications and change of brand name and with following label claim: **Each 1000gm contains:** **Sodium Chloride…35gm** **Magnesium Sulphate…35gm** **Potassium Chloride…400mg** **Furosemide…….20gm** **Calcium Carbonate…45gm**	
105.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceutical Pvt Ltd., 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Doxytil-BC Oral Liquid
	Composition	Each 1ml Contains: Tylosin Tartrate…100mg Doxycycline HCl…200mg Colistin Sulphate…450,000 IU Bromhexine HCl…4mg
	Diary No. Date of R& I & fee	Dy.No 7564 dated 29-05-2019 Rs.20,000/- dated 02-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1Liter, 5Liter, 10Liter and 25Liter; N/A
	Me-too status	Tycodox-Plus Liquid of M/s Attabak Pharmaceutical Islamabad. (Reg. No.058893)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet section** confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML

		• The firm has submitted that 1mg Colistin Sulphate is not less than 20000 IU.
	Decision: Approved upto pack size of 1Litre. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
106.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceutical Pvt Ltd., 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Sulfaras Oral Liquid
	Composition	Each 1ml contains: Enrofloxacin……..75mg Sulphamethoxy Pyridazine…75mg Sulphamethazine……50mg Trimethoprim…….25mg
	Diary No. Date of R& I & fee	Dy.No 6408 dated 17-05-2019 Rs.20,000/- dated 02-05-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 5Liter, 10Liter and 25Liter; N/A
	Me-too status	Enroprim-S Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No.106675) without Cinoxin
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet** section confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML • Upon clarification that Enrofloxacin (cinoxin) was mentioned throughout the dossier while cinoxin (ciprofloxacin) is registered brand of M/s Searle IV Solutions Lahore, the firm has submitted that: "*We used Enrofloxacin as raw material (active) in previous product which are registered and use for me-too status Cinoxin (Enrofloxacin) is mentioned. Nowadays, Cinoxin is not produced while Enrofloxacin is produced and available in market. Cinoxin is used as raw active material.* ***We used Enrofloxacin as active material so please consider as Enrofloxacin*** **"**
	Decision: Approved with innovator's specifications upto pack size of 1Litre.	
107.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceutical Pvt Ltd., 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Albamectin Oral Liquid
	Composition	Each 100ml contains: Albendazole…10gm Triclabendazol…12gm Ivermectin…0.2gm
	Diary No. Date of R& I & fee	Dy.No 6405 dated 17-05-2019 Rs.20,000/- dated 02-05-2019
	Pharmacological Group	Dewormer/Anthelmentic
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 5Liter, and 25Liter; N/A
	Me-too status	Levamectin Oral Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No.078279)

	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet** section confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML
	Decision: Approved with pack size upto 1Litre.	
108.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceutical Pvt Ltd., 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Anthazol CS Suspension
	Composition	Each 1ml Contains: Oxyclozanide…62.50mg Oxfendazole…22.65mg Cobalt Chloride…1.67mg Sodium Selenite…0.50mg
	Diary No. Date of R& I & fee	Dy.No 6409 dated 19-05-2019 Rs.20,000/- dated 02-05-2019
	Pharmacological Group	Dewormer/Anthelmentic, Minerals Supplement
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 5Liter, and 25Liter; N/A
	Me-too status	Oxfendaox Plus Oral Drench of M/s Baariq Pharmaceuticals, Lahore. (Reg. No.075786)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet** section confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML
	Decision: Approved with pack size upto 1Litre.	
109.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceutical Pvt Ltd., 25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Vermicid Oral Suspension
	Composition	Each 1ml contains: Oxfendazole…22.65mg Cobalt Sulphate…3.82mg Sodium Selenite…0.35mg
	Diary No. Date of R& I & fee	Dy.No 6406 dated 17-05-2019 Rs.20,000/- dated 02-05-2019
	Pharmacological Group	Dewormer/Anthelmentic, Minerals Supplement
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 5Liter, and 25Liter; N/A
	Me-too status	Oxfendacon Plus Drench of M/s Vetcon Pharmaceuticals (Pvt) Ltd, Bhimber, Azad Jamu Kashmir (Reg. No. 57194)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Antibiotic) Vet** section confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML
	Decision: Approved with pack size upto 1Litre and change of brand name.	
110.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceutical Pvt Ltd., 25-km, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	Albendaras Oral Liquid
	Composition	Each ml Contains: Albendazole…100mg
	Diary No. Date of R& I & fee	Dy.No 6407 dated 17-05-2019 Rs.20,000/- dated 02-05-2019
	Pharmacological Group	Dewormer/Anthelmentic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 5Liter, and 25Liter; N/A
	Me-too status	Albensel-10 Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043143)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral Liquid (Antibiotic) Vet** section confirmed vide panel inspection report based on inspection dated **10-03-2021** for renewal of DML
	Decision: Approved with pack size upto 1Litre.	
111.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	El-Trilev-Sc Drench
	Composition	Each ml Contains: Triclabendazole…120mg Levamisole……75mg Sodium Selenite…0.35mg Cobalt Sulphate…0.75mg
	Diary No. Date of R& I & fee	Dy.No 5558 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antiplatyhenmintics/ Anthelmentic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 450ml, and 1000ml; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise label claim/master formula in terms of salt form in line with reference product and adjust its weight as per salt factor in master formula accordingly. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

		• Full fee of registration for revision of label claim/ master formula, and finished product specifications. • Undertaking as per 251st meeting of Registration Board has not been provided.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Latest GMP Inspection report conducted within last three years.**	
112.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	El-Keto Injection 100mg/ml
	Composition	Each ml Contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy.No 5559 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	NSAID, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs. 7,500/- for revision of finished product specifications. • Undertaking as per 251st meeting of Registration Board has not been provided.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
113.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ketoproline Injection
	Composition	Each ml Contains: Oxytetracycline…200mg Ketoprofen…30mg
	Diary No. Date of R& I & fee	Dy.No 5556 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antibiotic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Could not be confirmed

	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest cGMP inspection report (conducted within the period of last three years) is required. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise label claim/master formula in terms of salt form in line with reference product and adjust its weight as per salt factor in master formula accordingly. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Full fee of registration for revision of label claim/ master formula, and finished product specifications. • Lidocain HCl is included in list of excipients mentioned in master formula and outline of method of manufacture while the same has not been reflected in label claim, clarify. • Undertaking as per 251st meeting of Registration Board has not been provided.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
114.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	El-Trilev Drench
	Composition	Each ml Contains: Triclabendazole…120mg Levamisole…75mg
	Diary No. Date of R& I & fee	Dy.No 5557 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antiplatyhenmintics/ Anthelmentic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 450ml, and 1000ml; Decontrolled
	Me-too status	ENDO SHELL LIQUID, Reg. No. 103929
	GMP status	GMP inspection dated 03-03-2021 grants renewal of DML.
	Remarks of the Evaluator [X]	• Firm has Oral Liquid (general)Veterianry section. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Revise label claim/master formula in terms of salt form in line with reference product and adjust its weight as per salt factor in master formula accordingly. • Full fee of registration for revision of label claim/ master formula, and finished product specifications.
	Decision: Approved with following label claim and with Innovator's Specifications:	

	"Each ml Contains: **Triclabendazole…120mg** **Levamisole HCl…75mg"** **Registration letter shall be issued after submission of fee of Rs.30,000/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
115.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tri-Mox LA 15% Injection
	Composition	Each ml Contains: Amoxicillin as Amoxicillin Trihydrate…150mg
	Diary No. Date of R& I & fee	Dy.No 6748 dated 21-05-2019 Rs.20,000/- dated 21-05-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml vials; Decontrolled
	Me-too status	Almox 15% LA of M/s Star Labs Lahore. (Reg. No. 020842)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Injection Section (Veterinary)** confirmed from Inspection report dated 11-05-2018 for renewal of DML. • Firm has revised finished product specification from inhouse to "BP Vet specifications" along with the fee of Rs. 7,500/- via deposit slip no 08281631231.
	Decision: Approved	
116.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Genta Prim Injection
	Composition	Each ml contains: Gentamycin Sulphate…30mg Trimethoprim…25mg Sulfadimidine…125mg
	Diary No. Date of R& I & fee	Dy.No 6757 dated 21-05-2019 Rs.20,000/- dated 21-05-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml vials; Decontrolled
	Me-too status	Gentabak-Plus Injection of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No.048167)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Injection Section (Veterinary)** confirmed from Inspection report dated 11-05-2018 for renewal of DML. • Firm has revised finished product specification from in-house to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 797973866.

		• **Gentamycin Sulphate…30gm/ml** is mentioned in label claim on form-5, while the referred generic product contains **Gentamycin as Sulphate.....30mg/ml.** Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm; or revise label claim in line with reference product and submit fee accordingly for revision of label claim/ master formula.
	Decision: Approved with following label claim and with Innovator's Specifications: **Each ml contains:** **Gentamycin as Sulphate…30mg** **Trimethoprim……25mg** **Sulfadimidine……125mg** **Registration letter shall be issued after submission of differential fee of Rs.22500/- for revision /pre-approval correction in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
117.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Hawk Enbro Liquid
	Composition	Each ml contains: Enrofloxacin…200mg Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 7202 dated 27-05-2019 Rs.20,000/- dated 27-05-2019
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 2.5Liter; Decontrolled
	Me-too status	Bromoflox Oral Solution of M/S Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073905)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML
	Remarks of the Evaluator [X]	• Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013. • The product is non-pharmacopoeial.
	Decision: Approved with Innovator's Specifications and with pack size upto 1Liter. Registration letter shall be issued after submission of fee of Rs.7500/- for revision /pre-approval correction in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
118.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Quinohawk Liquid
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…48 M.I.U
	Diary No. Date of R& I & fee	Dy.No 7201 dated 27-05-2019 Rs.20,000/- dated 27-05-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 2.5Liter; Decontrolled
	Me-too status	Poly Quin Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 075752)

	GMP status	▪ Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML
	Remarks of the Evaluator [X]	• Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013. • The product is non-pharmacopoeial. • Moreover, the firm has submitted that the theoretical potency of colistion sulphate is 800µg base activity/mg.
	Decision: Approved with Innovator's Specifications and with pack size upto 1Liter. Registration letter shall be issued after submission of fee of Rs.7500/- for revision /pre-approval correction in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
119.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Tydocol-B Oral Powder
	Composition	Each 100gm Contains: Tylosin Tartrate…10gm Doxycycline HCl…20gm Colistin Sulphate…3gm Bromhexine …1gm
	Diary No. Date of R& I & fee	Dy.No 7200 dated 27-05-2019 Rs.20,000/- dated 27-05-2019
	Pharmacological Group	Antibiotic/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, and 2500gm; Decontrolled
	Me-too status	Tylokail Powder of M/s Kailgon Agro Industries (Pvt) Ltd., Balochistan. (Reg. No. 079140)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML
	Remarks of the Evaluator [X]	• **Veterinary oral Powder (antibiotic) and Veterinary oral Powder (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013. • The product is non-pharmacopoeial.
	Decision: Approved with Innovator's Specifications and with pack size upto 1Kg. Registration letter shall be issued after submission of fee of Rs.7500/- for revision /pre-approval correction in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
120.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Euromint Liquid
	Composition	Each ml Contains: Vitamin A…30,000,000 IU Menthol…50gm Eucalyptus…50gm Peppermint…40gm
	Diary No. Date of R& I & fee	Dy.No 6159 dated 15-05-2019 Rs.20,000/- dated 15-05-2019
	Pharmacological Group	Supplement/ counterirratative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Fenetime Oral Solution of M/s Biogen Pharma, Rawat. (Reg. No. 063815)

	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has submitted fee Rs. 7,500/- for revision of finished product specifications via deposit slip no 041403599512. • The firm has submitted that Vitamin A Palmitate 1.7MIU/gram • Initially the firm has applied for formulation containing Vitamin A ……30,000,000 IU, Menthol…50gm, Eucalyptus…50gm, Peppermint…40gm/**ml**. However, the referred generic product contains same quantities as applied **per liter**. Now the firm has submitted following revised formulation as per reference product **Each Liter Contains:** **Vitamin A…30,000,000 IU** **Menthol…50gm** **Eucalyptus…50gm** **Peppermint…40gm** **Shortcomings:** ➢ Balance Fee Rs. 22,500/- for revision of formulation
	Decision: Referred to committee for review of formulation in grey area as product contains ingredients regulated as H&OTC product.	
121.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Thiacol 25% Liquid
	Composition	Each ml Contains: Thiamphenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 6158 dated 15-05-2019 Rs.20,000/- dated 15-05-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Thiafen Oral Liquid of M/s. Farm Aid Group, Haripur. (Reg. No.102204)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has submitted fee Rs. 7,500/- for revision of finished product specifications via deposit slip no 81799710.
	Decision: Approved with Innovator's Specifications with pack size upto 1Litre.	
122.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Avimec Oral Liquid
	Composition	Each ml Contains: Ivermectin…10mg

	Diary No. Date of R& I & fee	Dy.No 6156 dated 15-05-2019 Rs.20,000/- dated 15-05-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Ivotek Drench 1% of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 063601)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML.
	Decision: Approved with pack size upto 1Litre.	
123.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Bonaid Minerals Granular Powder
	Composition	Each Kg Contains: Calcium…155gm Phosphorus…135gm Magnesium…55gm Sodium…45gm Iron as Ferrous…1gm Zinc…..3gm Manganese…2gm Copper…0.6gm Cobalt…0.01gm Iodine…0.04gm
	Diary No. Date of R& I & fee	Dy.No 6160 dated 15-05-2019 Rs.20,000/- dated 15-05-2019
	Pharmacological Group	Macro and mineral mixture
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 20Kg and 25Kg; Decontrolled
	Me-too status	L.S. Minerals Powder of M/s Nawan Labs Karachi (Reg. No. 021306)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Powder (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has submitted fee Rs. 7,500/- for revision of finished product specifications via deposit slip no 0329580112.
	Decision: Deferred for complete salt form, requisite fee and generic status.	
124.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Tilmix Oral Solution
	Composition	Each ml Contains: Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 6157 dated 15-05-2019 Rs.20,000/- dated 15-05-2019
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Tilcosin solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 035150)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has claimed **manufacturer's specifications** and submitted fee Rs. 7,500/- for revision of finished product specifications via deposit slip no 28959731489.
	Decision: Approved with innovator's specifications.	
125.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-CT 20% WSP
	Composition	Each Gram Powder Contains: Chlortetracycline HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 5563 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antibacterial and anti-protozoal
	Type of Form	Form 5
	Finished product Specification	**USP** specifications
	Pack size & Demanded Price	100gm, 500gm, and 1000gm; As recommended by PRC (MOH)
	Me-too status	Velle CT 20% W.S. Powder of M/s K&K Pharmaceuticals, Lahore. (Reg. No. 043591)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved.	
126.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Amoxi Col WSP
	Composition	Each 100gm Powder Contains: Amoxicillin Sodium…10gm Colistin Sulphate…500,00,000 IU
	Diary No. Date of R& I & fee	Dy.No 5562 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, and 1000gm; As recommended by PRC (MOH)
	Me-too status	VELLE MOXYCOL W.S. POWDER. Reg. No. 043592
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder Penicillin section (veterinary)** confirmed vide panel inspection report

		for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved with Innovator's Specifications. **Registration letter shall be issued after submission of fee of Rs.7500/- for revision /pre-approval correction in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 and conversion of Colistin sulphate from IU to grams.**	
127.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Amcolist 120 WSP
	Composition	Each Gram Powder Contains: Amoxicillin Trihydrate…120mg Colistin Sulphate…10,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 7661 dated 30-05-2019 Rs.20,000/- dated 29-05-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm and 1000gm; As recommended by PRC (MOH)
	Me-too status	Could not be confirmed in the applied strength.
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder Penicillin section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications. • Provide conversion of Colistin sulphate from IU to grams.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Submission of conversion of Colistin sulphate from IU to grams.**	
128.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Bromox WSP
	Composition	Each Gram Contains: Doxycycline Hyclate…200mg Tylosin Tartrate…100mg Bromhexine HCl…24mg
	Diary No. Date of R& I & fee	Dy.No 6289 dated 16-05-2019 Rs.20,000/- dated 16-05-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1Kg; As recommended by PRC (MOH)
	Me-too status	Could not be confirmed in the applied strength.
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
129.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Sipra WSP
	Composition	Each 1000gm Powder contains: Spiramycin Adipate…75gm Lincomycin HCl…25gm
	Diary No. Date of R& I & fee	Dy.No 6290 dated 16-05-2019 Rs.20,000/- dated 16-05-2019
	Pharmacological Group	Antibiotic/ antiparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm and 1Kg; As recommended by PRC (MOH)
	Me-too status	Espira Powder of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No.105020)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision: Approved with Innovator's Specifications. **Registration letter shall be issued after submission of fee of Rs.7500/- for revision /pre-approval correction in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

130.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Erizine WSP
	Composition	Each Gram Powder Contains: Erythromycin Thiocyanate…200mg Sulfadiazine…150mg Trimethoprim…30mg
	Diary No. Date of R& I & fee	Dy.No 7663 dated 30-05-2019 Rs.20,000/- dated 29-05-2019
	Pharmacological Group	Antibiotic/ antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm and 1000gm; As recommended by PRC (MOH)
	Me-too status	**Could not be confirmed in the applied strength and combination.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
131.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Vesel E Liquid
	Composition	Each 1000ml Contains: Vitamin E Acetate (a-tocopherol) …200gm Sodium (as sodium selenite)…0.25gm
	Diary No. Date of R& I & fee	Dy.No 5560 dated 08-05-2019 Rs.20,000/- dated 08-05-2019
	Pharmacological Group	Antioxidant/ micronutrient
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000ml; As recommended by PRC (MOH)
	Me-too status	**Could not be confirmed in applied strength.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral liquid section (Veterinary)** confirmed from panel inspection report dated 05-12-2017 & 06-12-2017 for grant of GMP certificate

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
132.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cepfur Sterile Powder for Injection
	Composition	Each vial contains: Ceftiofur as Sodium…1gm
	Diary No. Date of R& I & fee	Dy.No 7566 dated 29-05-2019 Rs.20,000/- dated 27-05-2019
	Pharmacological Group	Antibacterial (Cephalosporin)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1's x 1gm; Decontrolled
	Me-too status	Ceftiofur Sodium for Injection of M/s Mehran International, Karachi (Reg. No. 049573)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 35787178.
	Decision: Deferred for approval of requisite manufacturing facility / section.	
133.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Tagafon Plus WSP
	Composition	Each gm contains: Trichlorfon…980mg
	Diary No. Date of R& I & fee	Dy.No 7939 dated 10-06-2019 Rs.20,000/- dated 31-05-2019
	Pharmacological Group	Organophosphate insecticide
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm, 10gm, 100gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Tri Gold WSP of M/s Attabak Pharma, Islamabad.(Reg. No. 049700)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection

		conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of **Oral Powder Sachet (General)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 799925699434.
	Decision: Approved with Innovator's Specifications.	
134.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Chlortiam WSP
	Composition	Each 100gm powder contains: Chlortetracycline HCl eq. to Chlortetracycline Base…20gm Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…36.45gm
	Diary No. Date of R& I & fee	Dy.No 8158 dated 12-06-2019 Rs.20,000/- dated 11-06-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm and 1000gm; As recommended by PRC (MOH)
	Me-too status	**Could not be confirmed in applied strength.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral dry powder section (Veterinary)** confirmed from panel inspection report dated 10-04-2019 & 23-04-2019 for grant of GMP certificate • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
135.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Peroxin Oral Solution
	Composition	Each ml Contains: Pefloxacin Methanesulfonate 139.6gm eq. to Pefloxacin……100gm
	Diary No. Date of R& I & fee	Dy.No 13215 dated 25-07-2019 Rs.20,000/- dated 25-07-2019
	Pharmacological Group	Quinolone antibiotic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Peperoxin Solution of M/s Hassan Brothers, Faisalabad (Reg. No.082807)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has claimed **manufacturer's specifications** along with fee of Rs.7,500/- vide challan No. 4378573184.
	Decision: Approved with innovator's specifications with pack size upto 1Liter.	
136.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Kiltix Solution
	Composition	Each ml contains: Deltamethrin…25mg
	Diary No. Date of R& I & fee	Dy.No 13213 dated 25-07-2019 Rs.20,000/- dated 25-07-2019
	Pharmacological Group	Ecto paracitiside
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Deltafaar Liquid of M/s Izfaar Pharmaceutical Industries, Lahore. (Reg. No.097876)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• Both "oral liquid" and "topical liquid" dosage forms are mentioned on form-5 while "topical liquid" is mentioned throughout the dossier; upon clarification regarding applied dosage form, the firm has submitted that **"***Kiltix is prescribed for external use i.e. spray, dip charging or topping up.*" However, the firm could not submit evidence of approval of topical liquid section.(The firm has submitted approval letter dated ------2015 for Liquid General section • The firm has claimed **manufacturer's specifications** along with fee of Rs.7,500/- vide challan No. 889074619. **Shortcomings:** • Evidence of approval of **Topical Liquid (General)** section / panel inspection report for renewal of DML
	Decision: Deferred for confirmation of approval of Topical Liquid (General) section.	
137.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Allout Oral Suspension
	Composition	Each 100ml contains: Albendazole…10gm Triclabendazole…12gm Ivermectin…0.2gm

	Diary No. Date of R& I & fee	Dy.No 13211 dated 25-07-2019 Rs.20,000/- dated 25-07-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter and 20Liter; Decontrolled
	Me-too status	Thunder Drench of M/s Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058941)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • The firm has claimed **manufacturer's specifications** along with fee of Rs.7,500/- vide challan No. 7415731515.
	Decision: Approved with innovator's specifications and change of brand name with pack size upto 1Liter.	
138.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Phantom Oral Powder
	Composition	Each gram contains: Phenoxymethylpenicillin…293mg eq. to Phenoxymethylpenicillin Potassium…325mg
	Diary No. Date of R& I & fee	Dy.No 13212 dated 25-07-2019 Rs.20,000/- dated 25-07-2019
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 20Kg, and 25Kg; Decontrolled
	Me-too status	Phenoxypen Water Soluble Powder of M/s Tec-Man International, Rawalpindi. (Reg. No.081303)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Powder (penicillin) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • Initially, Phenoxymethylpenicillin…293mg/G was mentioned in label claim on form-5 while Phenoxymethylpenicillin…325mg/G was mentioned in master formula; upon clarification the firm has submitted the correct formulation as mentioned below: **Each gram contains:** **Phenoxymethylpenicillin…293mg eq. to Phenoxymethylpenicillin Potassium…325mg** • Firm has submitted fee Rs. 30,000/- vide challan No. 55764995 for revision of master formula.
	Decision: Approved with USP specifications with pack size upto 1Kg.	
139.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Spalcodin Oral Powder

	Composition	Each Kg powder contains: Amoxicillin Trihydrate…100gm Lincomycin HCl…50gm Spectinomycin Sulphate…50gm
	Diary No. Date of R& I & fee	Dy.No 13214 dated 25-07-2019 Rs.20,000/- dated 25-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 500gm, 1Kg, 5Kg, 10Kg, 10Kg, and 20Kg; Decontrolled
	Me-too status	Spectomox-L oral powder of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No.102077)
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral Powder (penicillin) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML. • Initially, **Spectinomycin sulphate…50gm/Kg** was mentioned in label claim on form-5 while **Spectinomycin …50gm/Kg** was mentioned in master formula, upon clarification the firm has submitted the correct master formula along with fee Rs. 7500/- vide challan No. 021673791141 **Shortcomings:** • Balance fee Rs. 22,500/- for revision of master formula.
	Decision: Approved with innovator's specifications upto pack size 1Kg and with following label claim: **Each Kg powder contains:** **Amoxicillin Trihydrate…100gm** **Lincomycin HCl…50gm** **Spectinomycin Sulphate…50gm** **Registration letter shall be issued after submission of differential fee of Rs.22500/- for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
140.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Brom Plus Liquid
	Composition	Each ml contains: Bromhexine HCl…20mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 13082 dated 24-07-2019 Rs.20,000/- dated 23-07-2019
	Pharmacological Group	Mucolytic/anaesthetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml and 1000ml; As recommended by PRC (MOH)
	Me-too status	Bromo-Plus Liquid of M/s Elegance Pharmaceutical, Rawalpindi (Reg. No.073917)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• Approval of **oral liquid (General)** section confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML

	Decision: Approved with innovator's specifications. Firm shall submit fee of Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
141.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Brom Liquid
	Composition	Each ml contains: Bromhexine HCl…10mg Menthol…20mg
	Diary No. Date of R& I & fee	Dy.No 13085 dated 24-07-2019 Rs.20,000/- dated 23-07-2019
	Pharmacological Group	Mucolytic/anaesthetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml and 1000ml; As recommended by PRC (MOH)
	Me-too status	Bromotin Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 073999)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• Approval of **oral liquid (General)** section confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML
	Decision: Approved with innovator's specifications. Firm shall submit fee of Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
142.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Diver WSP
	Composition	Each Kg powder contains: Sulfadimerazine Sodium…860gm Diaveridine…105gm
	Diary No. Date of R& I & fee	Dy.No 13084 dated 24-07-2019 Rs.20,000/- dated 23-07-2019
	Pharmacological Group	Antibiotic/antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm sachets and 1000gm jars; As recommended by PRC (MOH)
	Me-too status	Fulstop Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 049524)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML
	Decision: Approved with innovator's specifications. Firm shall submit fee of Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
143.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Bromicta WSP

	Composition	Each 100gm Powder Contains: Bromhexine HCl…1gm Tartaric Acid…15gm
	Diary No. Date of R& I & fee	Dy.No 13083 dated 24-07-2019 Rs.20,000/- dated 23-07-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm and 1000gm jars; As recommended by PRC (MOH)
	Me-too status	Bromotaric Water Soluble Powder of M/s ICI Pakistan Limited, Lahore. (Reg. No. 089822)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML
	Decision: Approved with innovator's specifications. Firm shall submit fee of Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
144.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Nicta WSP
	Composition	Each 100gm contains: Nicotinamide…0.32gm Menadione Bisulfite…0.115gm Potassium Citrate…18gm Sodium Citrate…12gm Vitamin B1…0.03gm Vitamin B2…0.015gm Vitamin C…1.10gm
	Diary No. Date of R& I & fee	Dy.No 11470 dated 10-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm jar; As recommended by PRC (MOH)
	Me-too status	Anti Gumbo Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 046581)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML
	Decision: Approved with innovator's specifications. Firm shall submit fee of Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
145.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Doxybrotyl Powder
	Composition	Each 1000gm contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm

		Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 11142 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Tylobid Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075715)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 8314936611.
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
146.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Tyldoxbro powder
	Composition	Each 100gm contains: Doxycycline HCl…20gm Colistin Sulphate…50 MIU Tylosin Tartrate…10gm Bromhexine HCl…0.5gm
	Diary No. Date of R& I & fee	Dy.No 11139 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	B.G. Doxit Water Soluble Powder of M/s Biogen Pharma, Rawat. (Reg. No. 080147)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 77086925. • Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 10MIU= 500mg
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
147.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Mentfort V Solution

	Composition	Each 1000ml contains: Peppermint…40gm Eucalyptus…50gm Menthol…50gm Vitamin A…30000000 IU
	Diary No. Date of R& I & fee	Dy.No 11125 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Decongestant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, and 1000ml; As per DPC
	Me-too status	Fenetime Oral Solution of M/s Biogen Pharma,Rawat. (Reg. No. 063815)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 4581537301. • Provided conversion of Vitamin A from MIU to grams Vitamin A Palmitate 1.7MIU/gram
	Decision: Referred to committee for review of formulation in grey area as product contains ingredients regulated as H&OTC product.	
148.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Florfen Solution
	Composition	Each ml contains: Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 11129 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, and 1000ml; As per DPC
	Me-too status	Fenlor Solution of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071080)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 7329167371.
	Decision: Approved with innovator's specifications.	
149.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Mentbro Powder

	Composition	Each gm contains: Bromhexine HCl…20mg Menthol……..…4mg
	Diary No. Date of R& I & fee	Dy.No 11133 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Tusnil 2% Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075627)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 19176907.
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
150.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Jalc Plus Powder
	Composition	Each gram Contains: Aspirin…200mg Vitamin C…600mg Sodium Chloride…35mg Sodium Citrate…7mg
	Diary No. Date of R& I & fee	Dy.No 11132 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Electrolytes/ Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg; As per DPC
	Me-too status	Electro Ras Plus W/S Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 062188)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 1980709737. **Shortcomings:** • Justification/ clarification regarding compatibility of Acetylsalicyclic Acid with Vitamin C
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
151.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.

	Brand Name +Dosage Form + Strength	I-Bromen Solution
	Composition	Each ml contains: Menthol…20mg Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 11128 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, and 1000ml; As per DPC
	Me-too status	Bromotin Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 073999)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 2171964718.
	Decision: Approved with innovator's specifications.	
152.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Neocin 72 Powder
	Composition	Each kg contains: Neomycin Sulphate…720gm
	Diary No. Date of R& I & fee	Dy.No 11141 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Nobineo Oral Powder of M/s Noble Pharma Mirpur Azad Kashmir (Reg. No. 058726)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 3463918581.
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
153.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Bromoride Powder
	Composition	Each 100gm contains: Bromhexine HCl…5gm

	Diary No. Date of R& I & fee	Dy.No 11131 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Bromex Water Soluble Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 058891)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 51521673
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
154.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Tyldoxclin Powder
	Composition	Each 1000gm contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm
	Diary No. Date of R& I & fee	Dy.No 11140 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	DOT Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 069628)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 16025569.
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
155.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Neoflor Powder
	Composition	Each Kg contains: Neomycin Sulphate…150gm Florfenicol…100gm Oxytetracycline HCl…300gm
	Diary No. Date of R& I & fee	Dy.No 11136 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Noxyflor Water Soluble Powder of M/s Divine Pharmaceuticals, Lahore. (Reg. No. 087584)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 4573598960.
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
156.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-NCS Powder
	Composition	Each gm contains: Neomycin Sulphate…60mg Streptomycin Sulphate…20mg Chlortetracycline as HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 11134 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	NC STREP Powder of M/s Leads Pharma (Pvt) Ltd, Islamabad. (Reg. No. 079149)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 87528097.
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
157.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Colamox Powder
	Composition	Each 100gm contains: Spectinomycin as Sulphate…5gm Colistin Sulphate…50 MIU Amoxicillin Trihydrate…10gm Bromhexine HCl…0.5gm
	Diary No. Date of R& I & fee	Dy.No 11137 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	AS-Plus Water Soluble Powder of M/s Attabak Pharmaceutical Islamabad (Reg. No. 071063)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Penicillin Powder Oral section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 94440775. • Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 10MIU= 500mg
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
158.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Lincomix Powder
	Composition	Each 100gm contains: Lincomycin HCl…44gm
	Diary No. Date of R& I & fee	Dy.No 11135 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Licogrow-44 Oral Powder of M/s RAS Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 080157)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 53199310.
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
159.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Tcolidox Powder
	Composition	Each 1000gm contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 11130 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Polydox-T Oral Powder of M/s Biogen Pharma, Rawat. (Reg. No. 071019)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 0587282826. • Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 10MIU= 500mg
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
160.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Doxclin T Powder
	Composition	Each 100gm contains: Doxycycline HCl…20gm Colistin Sulphate…45 MIU Tylosin Tartrate…10gm Bromhexine HCl…0.4gm
	Diary No. Date of R& I & fee	Dy.No 11138 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; As per DPC
	Me-too status	Doxyline Water Soluble Powder of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 075776)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Dry Powder (General and Antibiotic) section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 587004436075. • Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 10MIU= 500mg
	Decision: Approved with innovator's specifications with pack size of upto 1Kg.	
161.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Enrocol B Solution
	Composition	Each 100ml contains: Enrofloxacin HCl…10gm Colistin Sulphate…5 MIU Bromhexine HCl…0.5%

	Diary No. Date of R& I & fee	Dy.No 11126 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, and 1000ml; As per DPC
	Me-too status	Could not be confirmed
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 2060509181. • Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 10MIU= 500mg **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
162.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bhobtian Chowk, Defence Road, 1-Km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Enrocil Solution
	Composition	Each 100ml contains: Enrofloxacin HCl…20gm Colistin Sulphate…4500000 IU
	Diary No. Date of R& I & fee	Dy.No 11127 dated 08-07-2019 Rs.20,000/- dated 08-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, and 1000ml; As per DPC
	Me-too status	Baxencol Liquid of M/s Baxter Pharmaceuticals, Karachi. (Reg. No. 073975)
	GMP status	cGMP certificate dated 13-04-2022 based on inspection conducted on 13-01-2022.
	Remarks of the Evaluator [X]	**Syrup General section** verified from panel inspection report for renewal of DML based on inspection dated 13-01-2022. • Firm has revised finished product specification from inhouse to **"as per innovator's specifications"** along with the fee of Rs. 7,500/- via deposit slip no 3472969037. • Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 10MIU= 500mg
	Decision: Approved with innovator's specifications.	

163.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Lincos-P 11% Powder
	Composition	Each 100gm contains: Lincomycin Monohydrate…11gm
	Diary No. Date of R& I & fee	Dy.No 12009 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	LINC-11 Oral Powder of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 093864)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 8317407563. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
164.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Paramax-C Oral Powder
	Composition	Each 100gm contains: Paracetamol…2gm Vitamin C…20gm Calcium Carbonate…4.5gm Magnesium Sulphate…3.5gm Potassium Chloride…4gm
	Diary No. Date of R& I & fee	Dy.No 12007 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Analgesic, stress controller
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	SPIN-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078239)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 3027034788.

		Shortcomings: • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
165.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tybrox 10 Oral Powder
	Composition	Each 1000gm contains: Doxycycline as HCl…200gm Tylosin Tartrate…100gm Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 12014 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg Bag; Decontrolled
	Me-too status	Biodox Forte Oral Powder of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 079874)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 52422053801. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
166.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Levosin 30 Powder
	Composition	Each gram contains: Levamisole HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 12010 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Levamin Powder of M/s Univet Pharmaceutical, Rawalpindi (Reg. No. 069644)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018

		• Firm has revised finished product specification from inhouse to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 21508620062. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
167.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Xedo-80 Oral Powder
	Composition	Each gram contains: Doxycycline Hyclate Eq. To Doxycycline…800mg
	Diary No. Date of R& I & fee	Dy.No 12019 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Doxyral 80% Water Soluble Powder of M/s Orient Animal Health (Pvt.) Limited, Karachi (Reg. No. 082504)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 49519388154. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
168.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Xedo-575 Oral Powder
	Composition	Each gram contains: Doxycycline Hyclate…575mg
	Diary No. Date of R& I & fee	Dy.No 12020 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Cydox Oral Powder of M/s ISIS Pharmaceuticals & Chemical Works, Karachi (Reg. No. 063525)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018

		• Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 92204362913. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
169.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Coolant Oral Powder
	Composition	Each 100gm contains: Paracetamol…20gm Vitamin C…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…12.5gm
	Diary No. Date of R& I & fee	Dy.No 12025 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Analgesic, Stress controller
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Para CE Oral Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 063812)
	GMP status	Not submitted
	Remarks of the Evaluator [x]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 60066419. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
170.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Marisil 300 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…150mg Florfenicol…150mg
	Diary No. Date of R& I & fee	Dy.No 12016 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled

	Me-too status	Oxy-Floro Water Soluble Powder of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080726)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 304691490887. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg Pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
171.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Amanta-10 Powder
	Composition	Each 100gm contains: **Amantadine HCl**…10gm
	Diary No. Date of R& I & fee	Dy.No 12017 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Amandin Water Soluble Powder of M/s Fizi Pharmaceuticals and Chemical Laboratories, Lahore. (Reg. No. 103819)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "as per innovator's specifications" along with the fee of Rs. 7,500/- via deposit slip no 69840062651. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
172.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Amanta-98 Powder
	Composition	Each 100gm contains: **Amantadine HCl**…98gm
	Diary No. Date of R& I & fee	Dy.No 12018 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Hansredin 98% Powder of M/s D-Haans Pharmaceuticals and Chemical Laboratories, Bhimber, Azad Kashmir. (Reg. No. 102207)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 44192889100. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
173.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Amicin 60 Powder
	Composition	Each Kg contains: Neomycin Sulphate…600gm
	Diary No. Date of R& I & fee	Dy.No 12011 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Aminoglycoside Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Neocin-S Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 069625)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 42620044349. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
174.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Amicin 70 Powder
	Composition	Each Kg contains: Neomycin Sulphate…70%
	Diary No. Date of R& I & fee	Dy.No 12012 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Aminoglycoside Antibiotic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Neocin Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 063714)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 97960066. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
175.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tybrox-2 Oral Powder
	Composition	Each 100gm contains: Doxycycline HCl…40gm Tylosin Tartrate…20gm Colistin Sulphate…10gm Bromhexine HCl…2gm
	Diary No. Date of R& I & fee	Dy.No 12013 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg Bag; Decontrolled
	Me-too status	Multidox Oral Powder of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 078395)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 4964231175. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto pack size 1Kg. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
176.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydox-70 C Water Soluble Powder

	Composition	Each 1000gm contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm Colistin Sulphate…500 MIU Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 12024 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg Bag; Decontrolled
	Me-too status	Fit Respi Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Islamabad. (Reg. No. 078268)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet)** section confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 61931658826. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years) • Provide conversion of Colistin Sulphate from MIU to grams.
	Decision: Approved with innovator's specification upto pack size 1Kg. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years and conversion of Colistin Sulphate from MIU to grams.	
177.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydox-70 Powder
	Composition	Each 1000gm contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy.No 12023 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg Bag; Decontrolled
	Me-too status	Tylobid Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075715)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet)** section confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 16751795. **Shortcomings:**

		• Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto pack size 1Kg. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
178.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydox 65 Powder
	Composition	Each 1000gm contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy.No 12022 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg Bag; Decontrolled
	Me-too status	TB-DOX Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075718)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Oral Dry Powder General (Vet) section confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 39024041. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto pack size 1Kg. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
179.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Levosin 20 Powder
	Composition	Each 100gm contains: Levamisole HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 12008 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	Leva Tech -20 W/S Powder of M/s Islamabad Pharmaceutical Products Islamabad (Reg. No. 022757)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Oral Dry Powder General (Vet) section confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along

		with the fee of Rs. 7,500/- via deposit slip no 4538055413. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
180.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Chlortet Plus Water Soluble Powder
	Composition	Each 1000gm contains: Neomycin Sulphate…70gm Colistin Sulphate…4gm Chlortetracycline HCl…80gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy.No 12006 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 5Kg, 10Kg, 25Kg Bag; Decontrolled
	Me-too status	NB-CIN Water Soluble Powder of M/s D-Maarson Pharmaceuticals, Islamabad (Reg. No. 078359)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Dry Powder General (Vet)** section confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 57760245. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Kg pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
181.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tydox-30 GP Oral Liquid
	Composition	Each 100ml contains: Doxycycline HCl…20gm Tylosin Tartrate…10gm Guaifenesin…20gm Aminophylline…8gm
	Diary No. Date of R& I & fee	Dy.No 12021 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibiotic/ Bronchodilator
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml, 100ml, 150ml, 250ml, 450ml, 500ml, 1000ml plastic bottle with sealed cap, 2.5liter, 5liter, 10liter, 25liter Can; Decontrolled
	Me-too status	Tyco-G Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 075704)

	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Liquid General** section confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 21104761677. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Liter pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
182.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Marisil 20 Liquid
	Composition	Each 100ml contains: Florfenicol…20gm
	Diary No. Date of R& I & fee	Dy.No 12015 dated 16-07-2019 Rs.20,000/- dated 16-07-2019
	Pharmacological Group	Antibiotic/ Bronchodilator
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml, 100ml, 250ml, 500ml, 1000ml plastic bottle with sealed cap, 2.5liter, 5liter, 10liter, 25liter Can; Decontrolled
	Me-too status	Floricol Liquid of M/s Inshal Pharmaceutical Industries, Islamabad (Reg. No. 073936)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• **Oral Liquid General** section confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018 • Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 7941017727. **Shortcomings:** • Latest cGMP inspection report (conducted within the period of last three years)
	Decision: Approved with innovator's specification upto 1Liter pack size. Registration letter will be issued after satisfactory GMP report by QA&LT Division within 3 years.	
183.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Danocin 2.5% injection
	Composition	Each ml Contains: Danofloxacin (as mesylate) …25mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 4162 dated 02-02-2018 Rs.20,000/- dated 29-01-2018 (**Duplicate fee challan attached**)
	Pharmacological Group	Quinolone antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; As per SRO

	Me-too status	Dflox Injection (50ml) of M/s Selmore Pharmaceuticals, Lahore. (Reg. No. 088087)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• Approval of **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. • The firm has revised finished product specifications from Manufacturer's to "**as per innovator's specifications**" without submitting fee.
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. Moreover, fee shall be verified as per procedure adopted by the Registration Board in its 285th meeting.	

Item No. XIV: Agenda of Evaluator-IX

184.	**Name and address of manufacture / Applicant**	**M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406)** **Tablet Section (General)**
	Brand Name + Dosage Form and Strength	POZER 15MG/1MG Tablet.
	Composition	Each Film Coated tablet contains; Pioglitazone Hydrochloride ……. 15 mg Glimepiride ……. 1 mg
	Dairy No. date of R &I fee	Dy. No. 15366 dated 07.03.2019. Fee paid vide voucher No. 0836419 dated 07.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose lowering drugs; ATC code: A10BD06.
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications.
	Pack size and Demand Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Not available in applied strength. In RRA the combination is available with 30 mg strength of Pioglitazone.
	Me-too-status	Piozer-G 15/1 Tablets Reg. No. 055163 M/s Hilton Pharma (Pvt) Ltd,, 13, Sector-15, Korangi Industrial Area, Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Pioglitazone and Glimepiride Tablets is present in USP, the firm shall revise specifications as per pharmacopoeia specifications. iii. The approval status of the product with the same strength (i.e. Pioglitazone (as HCl) 15 mg and Glimepiride…. 1 mg) in RRA shall be submitted. iv. Label claim needs revision as Pioglitazone is added in its salt form i.e. HCl. Also submit requisite fee (full fee) for change of salt form.
	)ecision: Deferred for following; • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of correct Form-5, revised specifications as per Pharmacopoeia and label claim declaring the strength of Pioglitazone in terms of base along with relevant fee for correction/pre-approval change in product specifications, label claim and Form 5 as per**	

	notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
185.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	POZER 15MG/2MG Tablet.
	Composition	Each Film Coated tablet contains; Pioglitazone Hydrochloride ……. 15 mg Glimepiride ……. 2 mg
	Dairy No. date of R &I fee	Dy. No. 15361 dated 07.03.2019. Fee paid vide voucher No. 0836415 dated 07.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose lowering drugs; ATC code: A10BD06.
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not available in applied strength. In RRA the combination is available with 30 mg strength of Pioglitazone.
	Me-too-status	Piozer-G 15/2 Tablets Reg. No. 050592 M/s Hilton Pharma (Pvt) Ltd,, 13, Sector-15, Korangi Industrial Area, Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Pioglitazone and Glimepiride Tablets is present in USP, the firm shall revise specifications as per pharmacopoeia specifications. iii. The approval status of the product with the same strength (i.e. Pioglitazone (as HCl) 15 mg and Glimepiride…. 2 mg) in RRA shall be submitted. iv. Label claim needs revision as Pioglitazone is added in its salt form i.e. HCl. Also submit requisite fee (full fee) for change of salt form.
	)ecision: Deferred for following; • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of correct Form-5, revised specifications as per Pharmacopoeia and label claim declaring the strength of Pioglitazone in terms of base along with relevant fee for correction/pre-approval change in product specifications, label claim and Form 5 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
186.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	POZER 30/4MG Tablet.
	Composition	Each tablet contains; Pioglitazone Hydrochloride …. 30 mg Glimepiride …….. 4 mg
	Dairy No. date of R &I fee	Dy. No. 15367 dated 07.03.2019. Fee paid vide voucher No. 0836420 dated 07.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose lowering drugs; ATC code: A10BD06.
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications.
	Pack size and Demand Price	10's As per SRO

	Approval status of product in Reference Regulatory Authorities	Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/4 mg uncoated tablet) FDA Approved
	Me-too-status	Piozer-G 30/4 Tablets Reg. No. 050691 M/s Hilton Pharma (Pvt) Ltd,, 13, Sector-15, Korangi Industrial Area, Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Pioglitazone and Glimepiride Tablets is present in USP, the firm shall revise specifications as per pharmacopoeia specifications. iii. Label claim needs revision as Pioglitazone is added in its salt form i.e. HCl. Also submit requisite fee (full fee) for change of salt form.
	)ecision: Deferred for submission of correct Form-5, revised specifications as per Pharmacopoeia and label claim declaring the strength of Pioglitazone in terms of base along with relevant fee for correction/pre-approval change in product specifications, label claim and Form 5 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
187.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME 2.0 mg Tablet
	Composition	Each Film coated Tablet contains; Glimepiride …….. 2 mg
	Dairy No. date of R &I fee	Dy. No. 15272 dated 07.03.2019. Fee paid vide voucher No. 0829587 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 2 mg Tablets MHRA Approved.
	Me-too-status	Amaryl tab 2 mg Reg. No. 019568 M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Glimepiride Tablets is present in pharmacopoeias; the firm shall revise specifications as per pharmacopoeia specifications. Submit requisite fee for the changes. iii. The product applied is a coated tablet, evidence of approval of coated tablet in RRA is required.
	Decision: Deferred for submission of correct Form-5, revised specifications as per Pharmacopoeia and label claim declaring the dosage form as film coated tablet along with relevant fee for correction/pre-approval change in product specifications, label claim and Form 5 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
188.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME 3.0 mg Tablet

	Composition	Each Film coated Tablet contains; Glimepiride …….. 3 mg
	Dairy No. date of R &I fee	Dy. No. 15271 dated 07.03.2019. Fee paid vide voucher No. 0829586 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 3 mg Tablets MHRA Approved.
	Me-too-status	Amaryl tab 3 mg Reg. No. 021094 M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Glimepiride Tablets is present in pharmacopoeias; the firm shall revise specifications as per pharmacopoeia specifications. Submit requisite fee for the changes. iii. The product applied is a coated tablet, evidence of approval of coated tablet in RRA is required.
	Decision: Deferred for submission of correct Form-5, revised specifications as per Pharmacopoeia and label claim declaring the dosage form as film coated tablet along with relevant fee for correction/pre-approval change in product specifications, label claim and Form 5 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
189.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME 4.0 mg Tablet
	Composition	Each Film coated Tablet contains; Glimepiride …….. 4 mg
	Dairy No. date of R &I fee	Dy. No. 15270 dated 07.03.2019. Fee paid vide voucher No. 0829585 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 4 mg Tablets MHRA Approved.
	Me-too-status	Amaryl tab 4 mg Reg. No. 021095 M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Glimepiride Tablets is present in pharmacopoeias; the firm shall revise specifications as per pharmacopoeia specifications. Submit requisite fee for the changes. iii. The product applied is a coated tablet, evidence of approval of coated tablet in RRA is required.
	Decision: Deferred for submission of correct Form-5, revised specifications as per Pharmacopoeia and label claim declaring the dosage form as film coated tablet along with relevant fee for	

	correction/pre-approval change in product specifications, label claim and Form 5 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
190.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	SPAS-CIBALGIN Tablets
	Composition	Each Film Coated Tablet Contains; Propyphenazone Ph. Eur. …….220 mg Hexahydroadiphenine HCl M.S ……20 mg
	Dairy No. date of R &I fee	Dy. No. 15303 dated 07.03.2019. Fee paid vide voucher No. 0835971 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Analgesic and antispasmodic. Could not be confirmed from ATC/DDD system.
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	10x10's As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too-status	Prohyd Tablet M/s Genome Pharmaceuticals (Pvt.) Ltd. Plot No. 16/1, Phase No. IV, Industrial Estate Hattar.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Provide details of the innovator along with evidence of approval in RRA. ii. Provide ATC Code for the drug combination applied.
	)ecision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
191.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMCOLAX TABLET
	Composition	Each Film Coated Tablet Contains; Bisacodyl …… 5 mg
	Dairy No. date of R &I fee	Dy. No. 15303 dated 07.03.2019. Fee paid vide voucher No. 0835971 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Contact Laxative ATC Code: A06AB02
	Type of form	Form-5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	2 x 10's. As per DRAP Policy.
	Approval status of product in Reference Regulatory Authorities	Bisacodyl 5mg Tablets Gastro-resistant Tablets MHRA Approved
	Me-too-status	DULCOLAX 5mg TAB M/s Merck (Pvt.) Ltd. 7-Jail Road, Quetta
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The product of innovator is gastro-resistant formulation and USP monograph is of delayed release tablets. The applied product is film coated. Justification or correction is required.
	Decision: Approved as per following label claim: "Each delayed release tablet contains; Bisacodyl …… 5 mg" • **The registration letter shall be issued after submission of revised formulation label and**	

	full fee for pre-approval changes by the firm for gastro-resistant/delayed release tablets as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
192.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Amenitec 5 mg Tablet
	Composition	Each Tablet Contains Enalapril Maleate …… 5 mg
	Dairy No. date of R &I fee	Dy. No. 15292 dated 07.03.2019. Fee paid vide voucher No. 0835957 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE inhibitors, plain ATC Code: C09AA02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO. As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Enalapril Maleate 5 mg Tablets MHRA Approved
	Me-too-status	Cardiotec 5 mg Tablet Reg. No. 010030 M/s Wilsons Pharmaceuticals (Pvt.) Ltd. Islamabad
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
193.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Amenitec 20 mg Tablet
	Composition	Each Tablet Contains Enalapril Maleate …… 20 mg
	Dairy No. date of R &I fee	Dy. No. 15290 dated 07.03.2019. Fee paid vide voucher No. 0835954 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE inhibitors, plain ATC Code: C09AA02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO. As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Enalapril Maleate 20 mg Tablets MHRA Approved
	Me-too-status	Cardiotec 20mg Tablet Reg. No. 007706 M/s Wilsons Pharmaceuticals (Pvt.) Ltd. Islamabad
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
194.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Metro 200mg Tablet

	Composition	Each film coated tablet Contains; Metronidazole B.P. …… 200mg
	Dairy No. date of R &I fee	Dy. No. 15368 dated 07.03.2019. Fee paid vide voucher No. 0836422 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Agents Against Amoebiasis And Other Protozoal Diseases, Nitroimidazole Derivatives. ATC Code: P01AB01
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metronidazole 200 mg Tablets Film-coated tablets MHRA Approved
	Me-too-status	Flagyl Tablets 200mg Reg. No. 000910
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
195.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Sartan 20mg tablet
	Composition	Each film coated tablet contains Telmisartan …… 20 mg
	Dairy No. date of R &I fee	Dy. No. 15234 dated 07.03.2019. Fee paid vide voucher No. 0758798 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II Antagonists, plain. ATC Code: C09CA07.
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO. As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Telmisartan 20mg Glenmark film-coated tablets MHRA Approved
	Me-too-status	Telsartan Tablet 20mg Reg. No. 045976 M/s CCL Pharmaceuticals (Pvt) Ltd., 62 Industrial Estate Kot Lakhpat Lahore
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
196.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Sartan 40mg tablet
	Composition	Each film coated tablet contains Telmisartan …… 40 mg
	Dairy No. date of R &I fee	Dy. No. 15279 dated 07.03.2019. Fee paid vide voucher No. 0829595 dated 02.03.2019, endorsed on 07.03.2019

	Pharmacological Group	Angiotensin II Antagonists, plain. ATC Code: C09CA07.
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO. As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Telmisartan 40mg Glenmark film-coated tablets MHRA Approved
	Me-too-status	Tesart 40mg Tablets Reg. No. 045082 M/s Bosch Pharmaceuticals, Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
197.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMDOMET 250 mg Tablet
	Composition	Each Film Coated Tablet contains; Methyldopa …… 250 mg
	Dairy No. date of R &I fee	Dy. No. 15300 dated 07.03.2019. Fee paid vide voucher No. 0835968 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	antiadrenergic agents ATC Code: C02AB
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Methyldopa 250mg Tablets BP Film coated tablets MHRA Approved.
	Me-too-status	Aldomet 250 mg Tablet Reg. No. 000311 M/s OBS (Pvt.) ltd.Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. On page 75 of the dossier, definition of Gastro-resistant Bisacodyl Tablets is given. This need correction along with provision of Requisite fee.
	Decision: Approved.	
198.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VERINE 200 mg Tablet
	Composition	Each Fim Coated Tablet Contains; Mebeverine HCl…….. 200 mg
	Dairy No. date of R &I fee	Dy. No. 15322 dated 07.03.2019. Fee paid vide voucher No. 0835991 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Drugs For Functional Gastrointestinal DisordersSynthetic Anticholinergics, Esters With Tertiary Amino Group ATC Code: A03AA04
	Type of form	Form-5-A
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Could not be found. The one provided by the applicant is a modified release

		capsule of Mebeverine.
	Me-too-status	Could not be verified.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The firm shall submit Approval status of product in Reference Regulatory Authorities. iii. The firm shall submit evidence of me too of same strength.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
199.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MLODI 5mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine Besylate ……. 5 mg
	Dairy No. date of R &I fee	Dy. No. 15241 dated 07.03.2019. Fee paid vide voucher No. 0758998 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Dihydropyridine derivatives ATC Code: C08CA01
	Type of form	Form-5-A
	Finished product specifications	In-House Specifications (Page 104)
	Pack size and Demand Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities	Norvasc 5 mg Tablets (amlodipine besylate equivalent to 5 mg of amlodipine per tablet). FDA Approved
	Me-too-status	Norvasc Tablet 5mg Reg. No. 011825 M/s Pfizer Pakistan Ltd., B-2-SITE Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The specifications of the applied product are present in pharmacopoeia and specifications applied are mfg specifications. This needs correction along with requisite fee. iii. The product of innovator is not film coated and the applied product is film coated. Justification is required.
	Decision: Deferred for submission of correct Form-5, revised drug product specifications as per Pharmacopoeia and revised master formulation as per innovator product along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
200.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	FEBUX 40mg Tablet
	Composition	Each Tablet contains; Febuxostat …….. 40 mg

	Dairy No. date of R &I fee	Dy. No. 15371 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836425 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Preparations inhibiting uric acid production ATC Code: M04AA03
	Type of form	Form-5-A
	Finished product specifications	In-house Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy
	Approval status of product in Reference Regulatory Authorities	Uloric tablets 40 mg. FDA Approved.
	Me-too-status	Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The specifications of the finished product is mentioned different at multiple points, on page 88 of the dossier In-house specifications are mentioned and on page 127 innovator's specifications are mentioned. This need to be clarified.
	Decision: Deferred for submission of correct Form-5 and drug product specifications along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
201.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	FEBUX 80mg Tablet
	Composition	Each Tablet contains; Febuxostat …….. 80 mg
	Dairy No. date of R &I fee	Dy. No. 15370 dated 07.03.2019. Fee paid vide voucher No. 0836424 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Preparations inhibiting uric acid production ATC Code: M04AA03
	Type of form	Form-5-A
	Finished product specifications	In-house Specifications (Page 88)
	Pack size and Demand Price	As per SRO and DRAP Policy
	Approval status of product in Reference Regulatory Authorities	Uloric tablets 80 mg. FDA Approved.
	Me-too-status	Adenuric Tablet 80mg Reg. No. 067034 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The specifications of the finished product is mentioned different at multiple points, on page 88 of the dossier In-house specifications are mentioned and on page 127 innovator's specifications are mentioned. This need to be clarified.
	Decision: Deferred for submission of correct Form-5 and drug product specifications along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
202.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)

	Brand Name + Dosage Form and Strength	MEBIN 500 mg Tablet
	Composition	Each Tablet Contains; Mebendazole ……. 500 mg
	Dairy No. date of R &I fee	Dy. No. 15359 dated 07.03.2019. Fee paid vide voucher No. 0836408 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTINEMATODAL AGENTS, Benzimidazole derivatives ATC Code: P02CA01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VERMOX 500 mg Chewable Tablets FDA Approved
	Me-too-status	Vermox 500 mg Reg. No. 009082 M/s Aspin Pharma (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The strength of 500mg mebendazole is approved in RRA in chewable form, the applied product is not chewable. Clarification is required.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 for revision of formulation and label as per innovator product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
203.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	APRIL 1.25 mg Tablet
	Composition	Each film Coated Tablet Contains; Ramipril …… 1.25 mg
	Dairy No. date of R &I fee	Dy. No. 15226 dated 07.03.2019. Fee paid vide voucher No. 0758790 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE Inhibitors, plain, ATC Code: C09AA05
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ramipril 1.25 mg Tablets MHRA Approved
	Me-too-status	Mevlon 1.25mg Tablet Reg. No. 045336 M/s Helix Pharma (Pvt) Ltd., A/56 SITE Mangopir Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
204.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	APRIL 5 mg Tablet

	Composition	Each Film Coated Tablet Contains; Ramipril…….. 5 mg
	Dairy No. date of R &I fee	Dy. No. 15258 dated 07.03.2019. Fee paid vide voucher No. 0829572 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE Inhibitors, plain, ATC Code: C09AA05
	Type of form	Form-5-A
	Finished product specifications	BP/USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Delix 5mg Tablets (Hoescht MR, Germany) Bfarm Germany Approved
	Me-too-status	Tritace 5mg Tablets Reg. No. 019565
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
205.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	APRIL 10 mg Tablet
	Composition	Each Film Coated Tablet Contains; Ramipril…….. 10 mg
	Dairy No. date of R &I fee	Dy. No. 15228 dated 07.03.2019. Fee paid vide voucher No. 0758792 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE Inhibitors, plain, ATC Code: C09AA05
	Type of form	Form-5-A
	Finished product specifications	BP/USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ramipril 10 mg Tablets MHRA Approved
	Me-too-status	Tritace 10mg Tablets Reg. No. 045390 M/s Sanofi-Aventis Pakistan Ltd., Plot No. 23 Sector 22 Korangi Industrial Area Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
206.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VENTO 2 mg Tablet
	Composition	Each Tablet Contains; Albuterol as sulfate …… 2 mg
	Dairy No. date of R &I fee	Dy. No. 15337 dated 07.03.2019. Fee paid vide voucher No. 0836430 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists, ATC Code: R03CC02
	Type of form	Form-5-A

	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Salbutamol Tablets BP 2mg Each tablet contains 2.4mg salbutamol sulfate equivalent to 2mg salbutamol. MHRA Approved
	Me-too-status	BRONKAL-2 TAB Reg. No. 011638 Each tablet contains:- SULBUTAMOL SULPHATE 2mg M/s Atco Laboratories Limited, B-18 S.I.T.E Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
207.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GABA 300 mg Tablet
	Composition	Each Tablet Contains; Gabapentin …… 300 mg
	Dairy No. date of R &I fee	Dy. No. 15324 dated 07.03.2019. Fee paid vide voucher No. 0835993 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX12
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Evidence of approval of Strength of 300 mg in tablet dosage form in RRA could not be verified.
	Me-too-status	Gabapen Tablet 300 mg Reg. No. 060555 M/s Batala Pharmaceuticals Gujranwala
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Strength of tablet in application at S. No. 4, page 4 is mentioned as 100 mg. It needs correction along with submission of requisite fee. iii. Evidence of approval of Strength of 300 mg in tablet dosage form in RRA is required.
	Decision: Deferred for submission of correct Form-5, clarification of applied strength along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
208.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VASTCOR 10 mg tablet
	Composition	Each Film Coated Tablet contains; Simvastatin…… 10 mg
	Dairy No. date of R &I fee	Dy. No. 15293 dated 07.03.2019. Fee paid vide voucher No. 0835960 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA01
	Type of form	Form-5-A

	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Simvastatin 10 mg Tablets Reg. No. 027757 Each film-coated tablet contains Simvastatin,10mg MHRA Approved.
	Me-too-status	Atcol 10 mg Tablets M/s Atco Laboratories B-18 S.I.T.E Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
209.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GALNAS 50 Tablet
	Composition	Each Film Coated Tablet Contains; Vildagliptin …… 50 mg
	Dairy No. date of R &I fee	Dy. No. 15265 dated 07.03.2019. Fee paid vide voucher No. 0829580 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, Dipeptidyl peptidase 4 (DPP-4) inhibitors ATC Code: A10BH02
	Type of form	Form-5-A
	Finished product specifications	In-House Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvus 50 mg Tablet MHRA Approved.
	Me-too-status	Galvus Tablets 50 mg Reg. No. 059038 M/s Novartis Pharma (Pakistan) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The applied product is film coated. The firm shall provide evidence of film coated tablets vildagliptin 50 mg approved in RRA.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Formulation as per innovator product.**	
210.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	IRBES 75 mg Tablet
	Composition	Each film Coated Tablet Contains; Irbesartan…….. 75 mg
	Dairy No. date of R &I fee	Dy. No. 15254 dated 07.03.2019. Fee paid vide voucher No. 0818379 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin-II Antagonists, Plain. ATC Code: C09CA04
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Irbesartan 75 mg film-coated tablets MHRA Approved.
	Me-too-status	Irecon Tablet 75 mg Reg. No. 039725 M/s Barret Hodgson Pakistan Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
211.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	HARTAN 160 mg Tablet
	Composition	Each Film Coated Tablet Contains; Valsartan ……. 160 mg
	Dairy No. date of R &I fee	Dy. No. 15283 dated 07.03.2019. Fee paid vide voucher No. 0829599 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ngiotensin II receptor blockers (ARBs), plain TC Code: C09CA03
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan 160 mg Film-Coated Tablets MHRA Approved
	Me-too-status	Nuval 160mg Tablet Reg. No. 066837 M/s PharmEvo (Pvt) Ltd., A-29 North West Industrial Zone Light Industrial Zone Port Qasim Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
212.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	OPRAM 20.0 MG Tablet
	Composition	Each Film Coated Tablet Contains; Escitalopram as Oxalate …… 20 mg
	Dairy No. date of R &I fee	Dy. No. 15266 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829581 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antidepressants, Selective serotonin reuptake inhibitors. ATC Code: N06AB10
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cipralex 20 mg film-coated tablets MHRA Approved
	Me-too-status	Cipralex Fim-Coated Tablets 20 mg Reg. No. 059035 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A.

		Application shall be submitted on correct form i.e. Form 5 ii. The strength of tablet at S. No 4 of page 4 is mentioned as 5 mg. This needs to be corrected along with submission of requisite fee.
	Decision: Deferred for submission of submission of correct Form-5 along with full fee. • **Submission of proper formulation and strength.**	
213.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VISTA 5mg Tablet
	Composition	Each Film Coated Tablet Contains; Rosuvastatin as calcium …. 5mg
	Dairy No. date of R &I fee	Dy. No. 15262 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829576 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA07
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rosuvastatin DAWA 5,10, 20 and 40 mg Film-Coated Tablets MHRA Approved.
	Me-too-status	Hyporose 5mg tablet Reg. No. 050413 M/s Mediate Pharmaceutical (Pvt.) Ltd. Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
214.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VENTO 8.0mg Extended-Release Tablets
	Composition	Each extended release tablet contains; Albuterol as Sulphate …….. 8 mg
	Dairy No. date of R &I fee	Dy. No. 15339 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836432 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists ATC Code: R03CC02
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VOSPIRE ER Albuterol sulfate eq 8 mg base FDA Approved.
	Me-too-status	Inhalerin SR Tab 8mg Reg. No. 029556 M/s Werrick Pharmaceuticals Islamabad.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The strength of tablet at S. No. 4, page 4 is

		mentioned as 2mg/tablet. This needs to be corrected along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of proper formulation and strength.**	
215.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MPROVEL 150mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains; Irbesartan …….…150 mg Hydrochlorothiazide …12.5 mg
	Dairy No. date of R &I fee	Dy. No. 15250 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0818370 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA04
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan Hydrochlorothiazide 150 mg/12.5 mg film coated tablets MHRA Approved
	Me-too-status	Arbi-D 150/12.5 tablet Reg. No 073772 M/s PharmEvo (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
216.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MPROVEL 300mg/25mg Tablet
	Composition	Each Film Coated Tablet Contains; Irbesartan …….…300 mg Hydrochlorothiazide …25 mg
	Dairy No. date of R &I fee	Dy. No. 15259 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829573 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA04
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan Hydrochlorothiazide 300 mg/25 mg film coated tablets MHRA Approved
	Me-too-status	Arbi-D 300mg/25mg tablet Reg. No 088175 M/s PharmEvo (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification	

	No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
217.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	CO-HARTAN 160 mg/12.5 mg Tablet
	Composition	Each Film Coated Tablet Contains; Valsartan…… 160 mg Hydrochlorothiazide….. 12.5 mg
	Dairy No. date of R &I fee	Dy. No. 15278 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829594 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA03
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan-Hydrochlorothiazide 160mg/12.5mg Film-Coated tablets. MHRA Approved
	Me-too-status	Nuval –D 160/12.5mg Tablet Reg. No.066839 M/s PharmEvo (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
218.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	CO-APRIL (2.5mg/12.5mg) (Ramipril/Hydrochlorothiazide) Tablet
	Composition	Each Tablet Contains; Ramipril (BP)…….. 2.5 mg Hydrochlorothiazide (BP)….12.5 mg
	Dairy No. date of R &I fee	Dy. No. 1357 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835453 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE inhibitors and diuretics ATC Code: C09BA05
	Type of form	Form-5
	Finished product specifications	Manufacturers Specifications.
	Pack size and Demand Price	28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ALTACE HCT Tablet Health Canada Approved.
	Me-too-status	Triatec HCT 2.5/12.5mg Tablet Reg. No. 043011 M/s Sanofi-Aventis Pakistan Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Specifications of Finished Product are mentioned as Manufacturers specifications.
	Decision: Approved with Innovator's Specifications.	
219.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME-M 2.0 mg / 500 mg Tablet

	Composition	Each Film Coated Tablet Contains; Glimepiride …… 2.0 mg Metformin HCl ……. 500 mg
	Dairy No. date of R &I fee	Dy. No. 15274 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829589 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs, metformin and sulfonylureas ATC Code: A10BD02
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too-status	Getformin Tablet 2mg+500mg Reg. No. 044126 M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	220. emark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Approval of product in Reference Regulatory Authorities is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
221.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEXET-D 60mg/120mg Tablet
	Composition	Each Film Coated Tablet Contains; Fexofenadine Hydrochloride USP ……60 mg Pseudoephedrine Hydrochloride USP …….. 120 mg
	Dairy No. date of R &I fee	Dy. No. 15306 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835974 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	pseudoephedrine, combinations ATC Code: R01BA52
	Type of form	Form-5
	Finished product specifications	Amros Specifications
	Pack size and Demand Price	1 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	ALLEGRA-D Fexofenadine hydrochloride and pseudoephedrine hydrochloride caplets (Sustained-Release) Caplets, 60 mg & 120 mg, Oral. The product approved by Health Canada is a Sustained release formulation.
	Me-too-status	Fexo-D Tablets Reg. No. 031607 M/s Hilton Pharma (Pvt.) Ltd.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Approval of product in Reference Regulatory Authorities is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities	
222.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406)

		Tablet Section (General)
	Brand Name + Dosage Form and Strength	FORMIN 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains; Metformin HCl …….500 mg Vildagliptin ……..50 mg
	Dairy No. date of R &I fee	Dy. No. 15264 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829578 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs. ATC Code: A10BD08
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Film Coated Tablets (50 mg vildagliptin and 500 mg metformin hydrochloride) Swissmedic Approved
	Me-too-status	Galvus Met 50/500mg tablet Reg. No. 078106 M/s Novartis Pharma (Pakistan) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
223.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	FORMIN 50/850mg Tablet
	Composition	Each Film Coated Tablet Contains; Metformin HCl …….850 mg Vildagliptin ……..50 mg
	Dairy No. date of R &I fee	Dy. No. 15246 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829579 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs. ATC Code: A10BD08
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Galvumet Film Coated Tablets (50 mg vildagliptin and 850 mg metformin hydrochloride) Swissmedic Approved
	Me-too-status	Vilfor 50/850mg tablet Reg. No. 106507 M/s Hi-Medic Pharmaceuticals (Pvt) Ltd Lahore
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
224.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	LO-HARD 50mg/12.5mg Tablet

	Composition	Each film coated tablet contains; Losartan Potassium …… 50 mg Hydrochlorothiazide…… 12.5 mg
	Dairy No. date of R &I fee	Dy. No. 15284 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829600 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics. ATC Code: C09DA01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LOSARTAN POTASSIUM /HYDROCHLOROTHIAZIDE 50MG /12.5MG TABLETS (Film Coated) MHRA Approved.
	Me-too-status	Thaitan-H 50mg/12.5mg Tablet Reg. No. 104788 M/s Jaens Pharmaceutical Industries (Pvt.) Ltd. Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
225.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	LO-HARD 100mg/12.5mg Tablet
	Composition	Each film coated tablet contains; Losartan Potassium …… 100 mg Hydrochlorothiazide…… 12.5 mg
	Dairy No. date of R &I fee	Dy. No. 15247 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0801927 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics. ATC Code: C09DA01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	COZAAR-COMP 100MG/12.5MG FILM-COATED TABLETS MHRA Approved.
	Me-too-status	Losmart-H 100mg/12.5mg Tablet Reg. No. 100198 M/s Scilife Pharma (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
226.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	COXIB 100mg Capsule
	Composition	Each Capsule Contains; Celecoxib …… 100 mg

	Dairy No. date of R &I fee	Dy. No. 15236 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0758800 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Coxibs. ATC Code: M01AH01
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CELEBREX 100-mg capsules FDA Approved
	Me-too-status	Celbex Capsules 100mg Reg. No. 028694 M/s Getz Pharma (Pvt) Ltd., 29-30 Sector 27 Korangi Industrial Area Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5. ii. In product summary dosage form is mentioned as "oral 100mg per tablet"
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of proper formulation and strength of applied product.**	
227.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	VERINE 10mg/ml Oral Solution
	Composition	Given for film coated tablets. (Page 110)
	Dairy No. date of R &I fee	Dy. No. 15311 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835980 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group. ATC Code: A03AA04
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mebeverine hydrochloride 50mg/5ml Oral Suspension MHRA Approved
	Me-too-status	Could not be verified.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Label claim is given for tablet, not for oral liquid. iii. Formulation approved in RRA is a suspension with label claim of 50mg/5ml. The applied label claim is different and dosage form is also different (oral solution). Evidence is required for applied formulation in RRA. iv. Evidence of Me-too product is also required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory**	

	authorities/agencies which were adopted by the Registration Board in its 275th meeting. • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Submission of proper formulation, label and specifications of the applied product.**	
228.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	Active-DM Syrup (Dextromethorphen 10 mg, Pseudoephedrine HCl 30 mg)
	Composition	Each 5ml contains; Dextromethorphan Hydrobromide…..... 10 mg Pseudoephdrine Hydrochloride …….. 30 mg Triprolidine hydrochloride……..…. 1.25 mg
	Dairy No. date of R &I fee	Dy. No. 15307 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835975 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antihistamines for systemic use ATC code: R06AX07
	Type of form	Form-5A
	Finished product specifications	Not mentioned.
	Pack size and Demand Price	60 ml, as per SRO
	Approval status of product in Reference Regulatory Authorities	Multi-Action ACTIFED Dry Coughs (oral Liquid) MHRA approved
	Me-too-status	Actifed DM Cough Syrup Reg. No. 007817 M/s GSK west Warf Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i.The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5. ii. Specifications of finished product are not mentioned in the application.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of proper specifications.**	
229.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form andStrength	ZINEDAL 5mg Syrup
	Composition	Each 5 ml contains Cetirizine dihydrochloride ……. 5 mg
	Dairy No. date of R &I fee	Dy. No. 15230 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0758794 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Piperizine derivatives ATC Code: R06AE07
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cetirizine Hydrochloride 5 mg/5 ml Oral Solution MHRA Approved.
	Me-too-status	Rigix Oral Solution Reg. No. 020308 M/s AGP (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e.

		Form 5 ii. In me-too and RRA Cetrizine hydrochloride is approved, not dihydrochloride. Label and formulation shall be corrected along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Or,** • **Correction for salt of API as per innovator product.**	
230.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	HYDROSIN-DM Syrup (diphenhydramine 5mg + Dextromethorphan 6.25) per 5 ml
	Composition	Each 5 ml contains; Diphenhydramine……5 mg Dextromethorphan……. 6.25 mg
	Dairy No. date of R &I fee	Dy. No. 15351 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835958 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	diphenhydramine, combinations. ATC Code: R06AA52
	Type of form	Form-5A
	Finished product specifications	Manufacturers Specifications.
	Pack size and Demand Price	120 mL, 450 mL. As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified for the applied strength
	Me-too-status	Cofex DM Syrup Reg. No 040625 M/s Wilson's Pharmaceuticals, 387-388 Sector I-9 Industrial Area Islamabad
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5. ii. The RRA approved formulations have salt forms in their label claim, (Dextromethorphan Hydrobromide, Diphenhydramine Hydrochloride). iii. The reference for this strength could not be verified in RRA.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
231.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	VENTO SYRUP 2mg/5ml
	Composition	Each 5 mL contains; Albuterol as Sulfate ……. 2 mg
	Dairy No. date of R &I fee	Dy. No. 15332 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836406 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists

		ATC Code: R03CC02
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	120 mL, As per SRO
	Approval status of product in Reference Regulatory Authorities	Ventolin Syrup MHRA Approved
	Me-too-status	Bronkal Syrup Reg. No. 013894 M/s Atco Laboratories Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted..
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. pharmacopoeial specifications of the applied formulation are available, specifications shall be revised to pharmacopoeial specs.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.**	
232.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Dry Powder Suspension Section (General)
	Brand Name + Dosage Form and Strength	ANZAL 100 mg Oral Solution
	Composition	Each 5 mL contains; Linezolid……. 100 mg
	Dairy No. date of R &I fee	Dy. No. 15321 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835990 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antibacterials. ATC Code: J01XX08
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Linezolid 100mg/5ml granules for oral suspension MHRA Approved.
	Me-too-status	Nezkil Dry Suspension Reg. No. 067037 M/s S.J. & G. Fazul Ellahi (Pvt.) Ltd. Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Applied product is oral solution, the formulation of linezolid is in form of granules for oral suspension.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of correct formulation as per innovator product.**	
233.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	METRO 200 mg/5ml Suspension
	Composition	Each 5mL contains; Metronidazole base…….... 200 mg
	Dairy No. date of R &I fee	Dy. No. 15374 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836428 dated 05.03.2019, endorsed on 07.03.2019

	Pharmacological Group	Antibacterial for Systemic use. ATC Code: J01XD01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metronidazole 200 mg/5 ml Oral Suspension Each 5 ml of oral suspension contains metronidazole benzoate equivalent to 200 mg of metronidazole MHRA Approved.
	Me-too-status	Diagyl Suspension Reg. No. 020229 M/s Swiss Pharmaceuticals (Pvt) Ltd., A-159 SITE North Karachi Scheme No. 33 Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Salt is not mentioned in label claim.
	Decision: Deferred for following: • **Submission of correct Form-5 along with full fee.** • **Correction for salt of API as per innovator product.**	
234.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	BENARIL SYRUP
	Composition	Each 5 ml contains; Ammonium Chloride……. 131.5 mg Chloroform… 22 mg Menthol……. 1 mg Sodium Citrate …….55 mg Diphenhydramine …..13.5 mg
	Dairy No. date of R &I fee	Dy. No. 15288 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835952 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	diphenhydramine, combinations ATC Code: R06AA52
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	120mL, 450mL. As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too-status	Could not be verified.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Salt of diphenhydramine is not mentioned. iii. Evidence of approval of formulation in RRA is required. iv. Evidence of approval of me-too is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory**	

	authorities/agencies which were adopted by the Registration Board in its 275th meeting. • **Correction for salt of API.**	
235.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Dry Powder Suspension Section (General)
	Brand Name + Dosage Form and Strength	AMCIN-C GRANULES For Oral Solution 75mg/ 5ml
	Composition	Label claim is given for capsule.
	Dairy No. date of R &I fee	Dy. No. 15330 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835999 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, Lincosamides ATC Code: J01FF01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cleocin FOR SOLUTION;ORAL FDA Approved.
	Me-too-status	Could not be confirmed.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Label claim of Capsule is given iii. Evidence of Me-too product is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Submission of proper label claim.**	
236.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	BALIN 50 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..50 mg
	Dairy No. date of R &I fee	Dy. No. 15277 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829593 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	14's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica® 50 mg hard capsules MHRA Approved.
	Me-too-status	Gabica 50 mg Capsule Reg. No. 048725 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e.

		Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
237.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	BALIN 150 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..150 mg
	Dairy No. date of R &I fee	Dy. No. 15313 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835982 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	14's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica® 150 mg hard capsules MHRA Approved.
	Me-too-status	Gabica 150 mg Capsule Reg. No. 048724 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
238.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	AMIN-C CAPSULE 300mg
	Composition	Each Capsule contains; Clindamycin as HCl…….. 300 mg
	Dairy No. date of R &I fee	Dy. No. 15327 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835996 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, Lincosamides ATC Code: J01FF01
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clindamycin 75, 150 and 300 mg Capsules, Hard. MHRA Approved.
	Me-too-status	Greenlin-300 Capsules Reg. No. 052448 M/s Evergreen Pharmaceuticals Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
239.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406)

		Cream / Ointment Section (General)
	Brand Name + Dosage Form and Strength	NITRA 20mg/g Cream
	Composition	Miconazole Nitrate 2.0 %
	Dairy No. date of R &I fee	Dy. No. 15347 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836440 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIFUNGALS FOR TOPICAL USE, Imidazole and triazole derivatives. ATC Code: D01AC02
	Type of form	Form-5A
	Finished product specifications	BP Specifications
	Pack size and Demand Price	10 gm, 20 gm. As per SRO
	Approval status of product in Reference Regulatory Authorities	Daktarin 2% Cream MHRA Approved
	Me-too-status	Myconit Cream Reg. No. 009936 M/s EPLA Laboratories (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Label claim of tablet is given instead of cream. iii. Strength needs to be correct to %w/w.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of proper label claim, formulation and specifications.**	
240.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406)
	Brand Name + Dosage Form and Strength	COOL GEL
	Composition	Contains; Lignocaine……..…..0.6% W/W Cetylpyridinium Chloride …. 0.02% W/W Menthol ……..….. 0.06 % W/W Eucalyptol …….……....0.1% V/W Ethanol……....33% V/W
	Dairy No. date of R &I fee	Dy. No. 15288 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835952 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Stomatological Preparation, ATC code: A01AD11
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	10 gm, 20 gm. As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified, more ingredients are used than provided reference.
	Me-too-status	Could not be verified, more ingredients are added than given me-too
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of RRA approval is required. iii. Evidence of me-too is required.

	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
241.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injectable Section (General)
	Brand Name + Dosage Form and Strength	AMROKET 30 MG INJECTION (Ampoule) (For toll manufacturing)
	Composition	Each Ampoule Contains; Ketorolac tromethamine ……. 30 mg
	Dairy No. date of R &I fee	Dy. No. 15373 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836427 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Acetic acid derivatives and related substances. ATC Code: M01AB15
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	1x1, as per SRO.
	Approval status of product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/ml Solution for Injection MHRA Approved.
	Me-too-status	Ketometa 30mg Injection Reg. No. 108436 M/s Lahore Chemical & Pharmaceutical Works Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5. ii. Volume of ampoule should be mentioned. Revise label claim accordingly along with requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of label claim as per innovator product.**	
242.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injectable Section (General)
	Brand Name + Dosage Form and Strength	AM-TOP 40mg Infusion
	Composition	Each Infusion Contains; Pantoprazole as Sodium sesquihydrate …. 40 mg
	Dairy No. date of R &I fee	Dy. No. 15288 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835952 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton Pump Inhibitor ATC Code: A02BC02
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10 infusions, As per SRO
	Approval status of product in Reference Regulatory Authorities	Infusion could not verified, powder for infusion is MHRA approved.
	Me-too-status	Could not be verified for infusion.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate

		valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i.The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Route of administration is mentioned as oral, needs correction. iii. Clarify whether product is infusion or powder for infusion. iv. Provide evidence of section approval for general vial dry powder filling. v. If product is in infusion form, provide evidence of RRA approval and Me-too status. Also mention volume of infusion in label claim
	Decision: Deferred for following; • **Submission of correct Form-5 having proper details of product applied along with full fee.** • **Evidence of approval of required manufacturing facility of "Dry powder Injection" Section from CLB.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.Correction for salt of API.**	
243.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injectable Section (General)
	Brand Name + Dosage Form and Strength	XAMIC 500mg Injection
	Composition	Each Injection Contains; Tranexamic Acid…… …. 500 mg
	Dairy No. date of R &I fee	Dy. No. 15285 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0818376 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIHEMORRHAGICS B02A ANTIFIBRINOLYTICS, Amino Acids ATC Code: B02AA02
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	2x 10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Cyklokapron Injection, 500mg/5ml Solution for injection MHRA approved.
	Me-too-status	Transamin –INJ Reg. No. 010452 M/s Hilton Pharma (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Route of Administration is mentioned as oral, needs correction. iii. Mention volume of ampoule and also revise label accordingly.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of label as per innovator product.**	
244.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injectable Section (General)
	Brand Name + Dosage Form and Strength	ANZAL 400 mg per 200 ml Infusion.

	Composition	Each 200 ml Contains; Linezolid…… …. 400 mg
	Dairy No. date of R &I fee	Dy. No. 15317 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835986 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antibacterials. ATC Code: J01XX08
	Type of form	Form-5A
	Finished product specifications	nnovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 2 mg/ml solution for infusion, 300 ml infusion bags contain 600 mg linezolid. MHRA Approved
	Me-too-status	Nezkil 200 mg Infusion, Reg. No. 048802 M/s S.J. & G. Fazul Ellahi (Pvt.) Ltd. Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted..
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Route of Administration is mentioned as oral, needs correction. iii. The product approved in RRA has strength of 600mg/300ml and have volume of 300 ml, whereas applied product is 400mg/200ml. Reference of RRA approval of applied product is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submit proper details about intended route of administration.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
245.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form andStrength	AMPITOR 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Atorvastatin as Calcium …..10mg
	Dairy No. date of R &I fee	Dy. No. 15257 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818375 dated 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA05
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor 10mg, 20mg, 40mg 80mg USFDA Approved.
	Me-too-status	Lipitor Tablet 10mg Reg. No. 023620 M/s Pfizer Laboratories Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of applied product is available in USP and applied specifications are innovator's. Justification or change of specifications is required along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.**	

	• **Revision of Specifications.**	
246.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMPITOR 20mg Tablet
	Composition	Each Film Coated Tablet Contains; Atorvastatin as Calcium …..20mg
	Dairy No. date of R &I fee	Dy. No. 15252 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818374 dated 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA05
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor 10mg, 20mg, 40mg 80mg USFDA Approved.
	Me-too-status	Lipitor Tablet 20mg Reg. No. 023621 M/s Pfizer Laboratories Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of applied product is available in USP and applied specifications are innovator's. Justification or change of specifications is required along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.**	
247.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMPITOR 40mg Tablets.
	Composition	Each Film Coated Tablet Contains; Atorvastatin as Calcium …..40mg
	Dairy No. date of R &I fee	Dy. No. 15248 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818368 dated 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA05
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor 10mg, 20mg, 40mg 80mg USFDA Approved.
	Me-too-status	Lipitor Tablet 40mg Reg. No. 023622 M/s Pfizer Laboratories Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	emark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of applied product is available in USP and applied specifications are innovator's. Justification or change of specifications is required along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.**	

	• **Revision of Specifications.**	
248.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	VERINE 200mg Capsule.
	Composition	Each Capsule Contains; Mebeverine HCl ….200 mg
	Dairy No. date of R &I fee	Dy. No. 15269 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0829584 dated 07.03.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group. ATC Code: A03AA04
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Mebeverine 200 mg modified release capsules (mebeverine hydrochloride) - PL 35533/0095 MHRA Approved.
	Me-too-status	Maravine 200mg Capsules Reg. No. 1088112 M/s MTI Medical (Pvt.) Ltd. Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Pellets Source: M/s Vision Pharmaceuticals. ii. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. iii. The formulation mentions pellets will be used, and label claim does not depict this. Evidence of RRA is also of modified release capsules which is not mentioned in label claim. Label claim needs to be revised accordingly along with submission of requisite fee (full fee).
	249. **Decision: Deferred for following;** • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
250.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GABA 100mg Tablet
	Composition	Each Film Coated Tablet Contains; Gabapentin …100mg
	Dairy No. date of R &I fee	Dy. No. 15325 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0835994 dated 07.03.2019
	Pharmacological Group	Other antiepileptics. ATC Code: N03AX12
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too-status	Kendis Tablet 100mg Reg. No. 049035 M/s Martin Dow Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form

		i.e Form 5, currently Form 5-A is submitted. ii. Evidence of RRA approval of product having strength of 100mg in tablet form is required.
	Decision: Deferred for following: • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
251.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GABA 400mg Tablet
	Composition	Each Tablet Contains; Gabapentin …400mg
	Dairy No. date of R &I fee	Dy. No. 15323 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0835992 dated 07.03.2019
	Pharmacological Group	Other antiepileptics. ATC Code: N03AX12
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too-status	Kendis Tablet 400mg Reg. No. 049037 M/s Martin Dow Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Evidence of RRA approval of product is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
252.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	METFOR 250mg Tablet
	Composition	Each Film Coated Tablet Contains; Metformin HCl ……. 250mg
	Dairy No. date of R &I fee	Dy. No. 15276 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0801926 dated 07.03.2019
	Pharmacological Group	Biguanides ATC Code: A10BA02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Glucophage Tablet 250mg Reg. No. 013365 M/s Martin Dow Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. The product approved in RRA is uncoated tablet.

		Applied product is film coated. Justification or correction along with submission of requisite fee is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or,** • **Revision of formulation as per innovator product.**	
253.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	METFOR 500mg Tablet
	Composition	Each Film Coated Tablet Contains; Metformin HCl ……. 500mg
	Dairy No. date of R &I fee	Dy. No. 15243 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0801924 dated 02.03.2019 endorsed on 07.03.2019
	Pharmacological Group	Biguanides ATC Code: A10BA02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metformin 500, 850 and 1000mg film-coated tablets PL 49230/0001-3 MHRA Approved.
	Me-too-status	Glucophage Tablet 500mg Reg. No. 000552 M/s Martin Dow Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
254.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	METFOR 850mg Tablet
	Composition	Each Film Coated Tablet Contains; Metformin HCl ……. 850mg
	Dairy No. date of R &I fee	Dy. No. 15256 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818382 dated 02.03.2019 endorsed on 07.03.2019
	Pharmacological Group	Biguanides ATC Code: A10BA02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metformin 500, 850 and 1000mg film-coated tablets PL 49230/0001-3 MHRA Approved.
	Me-too-status	Exermet Tablet 850mg Reg. No. 098913 M/s Aspin Pharma Karachi..
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification	

	No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
255.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	METFOR 1000mg Tablet
	Composition	Each Film Coated Tablet Contains; Metformin HCl ……. 1000mg
	Dairy No. date of R &I fee	Dy. No. 15245 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0801926 dated 07.03.2019
	Pharmacological Group	Biguanides ATC Code: A10BA02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Metformin 500, 850 and 1000mg film-coated tablets PL 49230/0001-3 MHRA Approved.
	Me-too-status	Glucophage Tablet 1Gm Reg. No. 025488 M/s Merck Quetta
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
256.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	VENTO 4.0mg Tablet
	Composition	Each Tablet Contains; Albuterol as Sulfate …… 4mg
	Dairy No. date of R &I fee	Dy. No. 15338 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0836431 dated 07.03.2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists, Salbutamol ATC Code: R03AC02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Salbutamol Tablets BP 4mg MHRA Approved.
	Me-too-status	Ventolin Tablet 2mg Reg. No. 000286 M/s GSK Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
257.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	MPROVEL 300mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains; Irbesartan …….. 300mg Hydrochlorothiazide. 12.5mg

	Dairy No. date of R &I fee	Dy. No. 15249 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818369 dated 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA04
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan and Hydrochlorothiazide Dr. Reddys 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg Film-coated Tablets (Irbesartan and hydrochlorothiazide) - UK/H/2639/001-3/DC; PL 08553/0404-6 MHRA Approved.
	Me-too-status	Arbi-D 300/12.5 Reg. No. 073771 M/s PharmEvo (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
258.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and trength	AMCIN-C Capsule 150mg
	Composition	Each Capsule Contains; Clindamycin as HCl…. 150mg
	Dairy No. date of R &I fee	Dy. No. 15366 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0836419 dated 07.03.2019
	Pharmacological Group	MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS ATC Code: J01FF01
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clindamycin 150 mg Capsules, Hard MHRA Approved.
	Me-too-status	Clidam 150mg Capsule Reg. No. 094956 M/s Parkar Pharma Kotri.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
259.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and trength	BALIN 75 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..75 mg
	Dairy No. date of R &I fee	Dy. No. 15312 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835981 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications

	Pack size and Demand Price	14's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and 300mg Capsules, hard (pregabalin) - PL 44041/0065-0072 MHRA Approved.
	Me-too-status	Gabica 75 mg Capsule Reg. No. 047365 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
260.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and trength	BALIN 300 MG Capsule
	Composition	Each Capsule Contains; Pregabalin ……..300 mg
	Dairy No. date of R &I fee	Dy. No. 15314 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835983 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antiepileptics ATC Code: N03AX16
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	14's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Pregabalin Noumed 25, 50, 75, 100, 150, 200, 225 and 300mg Capsules, hard (pregabalin) - PL 44041/0065-0072 MHRA Approved.
	Me-too-status	Gabica 300 mg Capsule Reg. No. 047368 M/s Getz Pharma (Pvt) Ltd Karachi
	GMP Status	Inspection report dated 18.07.2018 is attached which is older than 3 years.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
261.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	OPRAM 5.0mg Tablets
	Composition	Each Film Coated Tablet Contains; Escitalopram as Oxalate ….. 5mg
	Dairy No. date of R &I fee	Dy. No. 15267 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0829582 dated 07.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	Me-too-status	Cipralex Film-Coated Tablet 5mg Reg. No. 059033 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.

	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
262.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	OPRAM 10mg Tablets
	Composition	Each Film Coated Tablet Contains; Escitalopram as Oxalate ….. 10mg
	Dairy No. date of R &I fee	Dy. No. 15268 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0829583 dated 07.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code: N06AB10
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	Me-too-status	Cipralex Film-Coated Tablet 10mg Reg. No. 028467 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	)ecision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
263.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	POZER 30mg/2mg Tablet.
	Composition	Each tablet contains; Pioglitazone (as Hydrochloride) …. 30 mg Glimepiride …….. 2 mg
	Dairy No. date of R &I fee	Dy. No. 15362 dated 07.03.2019. Fee paid vide voucher No. 0836416 dated 07.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose lowering drugs; ATC code: A10BD06.
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications.
	Pack size and Demand Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Duetact (Pioglitazone hydrochloride and glimepiride) tablets (30 mg/2 mg uncoated tablet) FDA Approved
	Me-too-status	Piozer-G 30/2 Tablets Reg. No. 050690 M/s Hilton Pharma (Pvt) Ltd,, 13, Sector-15, Korangi Industrial Area, Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Pioglitazone and Glimepiride Tablets is present in USP, the firm shall revise

		specifications as per pharmacopoeia specifications along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.**	
264.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	POZER 15mg/4mg Tablet.
	Composition	Each Film Coated Tablet contains; Pioglitazone (as Hydrochloride) …. 15 mg Glimepiride …….. 4 mg
	Dairy No. date of R &I fee	Dy. No. 15363 dated 07.03.2019. Fee paid vide voucher No. 0836417 dated 07.03.2019
	Pharmacological Group	Drugs used in diabetes, combinations of oral blood glucose lowering drugs; ATC code: A10BD06.
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications.
	Pack size and Demand Price	10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Cannot be verified for the applied strength.
	Me-too-status	Piozer-G 15/4 Tablets Reg. No. 055167 M/s Hilton Pharma (Pvt) Ltd,, 13, Sector-15, Korangi Industrial Area, Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Pioglitazone and Glimepiride Tablets is present in USP, the firm shall revise specifications as per pharmacopoeia specifications along with submission of requisite fee. iii. Evidence of product approval in RRA with applied strength is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
265.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	CANDEN 8mg Tablet
	Composition	Each Film Coated Tablet Contains; Candesartan Cilexetil …. 8mg
	Dairy No. date of R &I fee	Dy. No. 15281 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0829597 dated 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code: C09CA06
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Candesartan cilexetil 4 mg, 8 mg, 16 mg and 32 mg Tablets - PL 35084/0002-9; UK/H/4347 & 4626/001-4/DC MHRA Approved.

	Me-too-status	Cansar 8mg Tablet Reg. No. 034306 M/s Pharmatec Pakistan Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e. Form 5, currently Form 5-A is submitted. ii. Evidence of product approved in RRA is of uncoated tablets, applied product is film coated. Justification or correction is required along with submission of requisite fee. iii. Monograph of applied product is available in USP and innovators specifications are applied. Justification or change of specs is required along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
266.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	CANDEN 16mg Tablet
	Composition	Each Film Coated Tablet Contains; Candesartan Cilexetil …. 16mg
	Dairy No. date of R &I fee	Dy. No. 15260 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0829574 dated 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code: C09CA06
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Candesartan cilexetil 4 mg, 8 mg, 16 mg and 32 mg Tablets - PL 35084/0002-9; UK/H/4347 & 4626/001-4/DC MHRA Approved.
	Me-too-status	Cansaar 16mg Tablet Reg. No. 033683 M/s Pharmatec Pakistan Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e. Form 5, currently Form 5-A is submitted. ii. Evidence of product approved in RRA is of uncoated tablets, applied product is film coated. Justification or correction is required along with submission of requisite fee. iii. Monograph of applied product is available in USP and innovators specifications are applied. Justification or change of specs is required along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
267.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)

	Brand Name + Dosage Form and trength	OPTADON Tablet 175mg/25mg
	Composition	Each Tablet Contains; Propyphenazone ……. 175mg Caffeine ……. 25mg
	Dairy No. date of R &I fee	Dy. No. 15308 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0835976 dated 07.03.2019
	Pharmacological Group	OTHER ANALGESICS AND ANTIPYRETICS, ATC Code: N02BB54
	Type of form	Form 5
	Finished product specifications	
	Pack size and Demand Price	10x20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Optalidon Tablet Reg. No. 002406 M/s GSK Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Specifications of the Finished product are not defined. ii. Evidence of approval of applied formulation in Reference Regulatory Authority as defined by Registration Board is required.
	Decision: Deferred for following; • **Submission of Specifications of finished product.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
268.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MATA PLUS Tablet 50mg/1000mg
	Composition	Each Film Coated Tablet Contains; Sitagliptin as Phosphate monohydrate…… 50mg Metformin HCl……..... 1000mg
	Dairy No. date of R &I fee	Dy. No. 15244 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0801925 dated 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD07
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	anumet Tablets MHRA Approved.
	Me-too-status	Treviamet 50mg 1000mg Tablet Reg. No. 055444 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
269.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	MATA PLUS Tablet 50mg/500mg

	Composition	Each Film Coated Tablet Contains; Sitagliptin as Phosphate monohydrate…… 50mg Metformin HCl……..... 500mg
	Dairy No. date of R &I fee	Dy. No. 15237 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0758993 dated 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code: A10BD07
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	anumet Tablets MHRA Approved.
	Me-too-status	Treviamet 50mg 500mg Tablet Reg. No. 055443 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
270.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	AM-TOP 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains; Pantoprazole as sodium sesquihydrate…… 20mg
	Dairy No. date of R &I fee	Dy. No. 15346 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0836439 dated 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 20 and 40mg gastro-resistant tablet; PL 49445/0026; PL 49445/0027 MHRA Approved.
	Me-too-status	Neege 20mg Tablet Reg. No. 079531 M/s Sami Pharmaceuticals (Pvt) Ltd Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
271.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	AM-TOP 40mg Tablet
	Composition	Each Enteric Coated Tablet Contains; Pantoprazole as sodium sesquihydrate…… 40mg
	Dairy No. date of R &I fee	Dy. No. 15340 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0836433 dated 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC02
	Type of form	Form 5-A
	Finished product specifications	USP Specifiations
	Pack size and Demand Price	10's As per SRO

	Approval status of product in Reference Regulatory Authorities	Pantoprazole 20 and 40mg gastro-resistant tablet; PL 49445/0026; PL 49445/0027 MHRA Approved.
	Me-too-status	Neege 40mg Tablet Reg. No. 039504 M/s Sami Pharmaceuticals (Pvt) Ltd Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
272.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Topical Section (General/steroidal)
	Brand Name + Dosage Form and trength	BETNASOL Cream 0.1%
	Composition	Each gram contains; Betamethasone (as valerate)….1.0mg
	Dairy No. date of R &I fee	Dy. No. 15366 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0836419 dated 07.03.2019
	Pharmacological Group	CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, CORTICOSTEROIDS, PLAIN, Corticosteroids, potent (group III) ATC Code: D07AC01
	Type of form	Form 5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10grams, As per SRO
	Approval status of product in Reference Regulatory Authorities	Betnovate Cream MHRA Approved.
	Me-too-status	Betnovate Cream Reg. No. 000256 M/s GSK Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Pack sizes are not mentioned. ii. %age strength is not mentioned.
	Decision: Approved. **The registration letter shall be issued after submission of pack sizes along with fee for pre-approval change.**	
273.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and trength	VENTO SYRUP 1mg/5ml
	Composition	Each 5ml Contains; Albuterol as Sulfate ……1mg
	Dairy No. date of R &I fee	Dy. No. 15286 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0818377 dated 07.03.2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists. ATC Code: R03CC02
	Type of form	Form 5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	120ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form

		i.e Form 5, currently Form 5-A is submitted. ii. Salbutamol oral Solution monograph is available in pharmacopoeia yet innovator's specifications are applied. Justification or correction along with requisite fee is required. iii. Evidence of product approval in RRA having strength of Strength of 1mg/5ml is required. iv. Evidence of me-too having strength of Strength of 1mg/5ml is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting..**	
274.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and trength	Hydrosin Syrup
	Composition	Each 5ml Contains; Aminophylline……..32mg Diphenhydramine…….8mg Ammonium Chloride …..30mg Menthol……0.98mg
	Dairy No. date of R &I fee	Dy. No. 15352 dated 07.03.2019. Fee paid Rs. 20000/- vide Slip No. 0835959 dated 07.03.2019
	Pharmacological Group	OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, Xanthines ATC Code: R03DA55
	Type of form	Form 5-A
	Finished product specifications	Manufacturer's Specifications.
	Pack size and Demand Price	120ml, 450ml
	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	Hydryllin Syrup Reg. No. 000016 M/s Searle Company Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Evidence of product approval in RRA is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
275.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	HARTAN 320 mg Tablet
	Composition	Each Film Coated Tablet Contains; Valsartan ……. 320 mg
	Dairy No. date of R &I fee	Dy. No. 15282 dated 07.03.2019. Fee paid vide voucher No. 0829598 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ngiotensin II receptor blockers (ARBs), plain TC Code: C09CA03
	Type of form	Form-5-A

	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VALSARTAN 320 MG FILM-COATED TABLETS 320 MG FILM-COATED TABLET - PL 08553/0703 MHRA Approved
	Me-too-status	Valbar 320mg Tablet Reg. No. 086704 M/s Barrett Hodgson Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
276.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	HARTAN 80 mg Tablet
	Composition	Each Film Coated Tablet Contains; Valsartan ……. 80 mg
	Dairy No. date of R &I fee	Dy. No. 15376 dated 07.03.2019. Fee paid vide voucher No. 0818367 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ngiotensin II receptor blockers (ARBs), plain TC Code: C09CA03
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VALSARTAN 80 MG FILM-COATED TABLETS 80 MG FILM-COATED TABLET - PL 08553/0700 MHRA Approved
	Me-too-status	Valbar 80mg Tablet Reg. No. 086702 M/s Barrett Hodgson Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
277.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	CARBA 200mg Tablet
	Composition	Each Tablet Contains; Carbamazepine ……. 200mg
	Dairy No. date of R &I fee	Dy. No. 15287 dated 07.03.2019. Fee paid vide voucher No. 0818381 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	NTIEPILEPTICS, Carboxamide derivatives TC Code: N03AF01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	50's, As per SRO
	Approval status of product in Reference Regulatory Authorities	CARBAMAZEPINE NOUMED 200 MG TABLETS - PL 44041/0035. MHRA Approved.
	Me-too-status	Mazetol Tablets Reg. No. 083998 M/s Cibex (Pvt.) Ltd. Karachi.

	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
278.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Sartan 80mg tablet
	Composition	Each film coated tablet contains Telmisartan …… 80 mg
	Dairy No. date of R &I fee	Dy. No. 15232 dated 07.03.2019. Fee paid vide voucher No. 0829596 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II Antagonists, plain. ATC Code: C09CA07.
	Type of form	Form-5A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO. As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Telmisartan Glenmark Generics/ Telmisartan Glenmark 20 mg, 40 mg and 80 Film-coated Tablets - PL 25258/0024-0026, PL 25258/0072 -0077; UK/H/2633/001-3/DC, UK/H/4197-8/001-3/DC MHRA Approved
	Me-too-status	Telsartan Tablet 80mg Reg. No. 045971 M/s CCL Pharmaceuticals (Pvt) Ltd., 62 Industrial Estate Kot Lakhpat Lahore
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
279.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	METRO 400mg Tablet
	Composition	Each film coated tablet Contains; Metronidazole B.P. …… 400mg
	Dairy No. date of R &I fee	Dy. No. 15364 dated 07.03.2019. Fee paid vide voucher No. 0836418 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Agents Against Amoebiasis And Other Protozoal Diseases, Nitroimidazole Derivatives. ATC Code: P01AB01
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	METRONIDAZOLE 400 MG FILM-COATED TABLETS - PL 43461/0068 MHRA Approved
	Me-too-status	Flagyl Tablets 400mg Reg. No. 000827
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A.

		Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
280.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	ANZAL 400mg Tablet
	Composition	Each Film Coated Tablet Contains; Linezolid…… 400mg
	Dairy No. date of R &I fee	Dy. No. 15320 dated 07.03.2019. Fee paid vide voucher No. 0835989 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	)ther antibacterials TC Code: J01XX08
	Type of form	Form-5-A
	Finished product specifications	Innovators's Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too-status	Nezkil Tablet 400mg Reg. No. 034783 M/s SJ&G Fazul Ellahi Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Valid Evidence of RRA Approval is required for strength of 400mg.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
281.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	GLIME-M 1.0 mg / 500 mg Tablet
	Composition	Each Film Coated Tablet Contains; Glimepiride …… 1 mg Metformin HCl ……. 500 mg
	Dairy No. date of R &I fee	Dy. No. 15275 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829591 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs, metformin and sulfonylureas ATC Code: A10BD02
	Type of form	Form-5A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too-status	Getformin Tablet 1mg+500mg Reg. No. 044360 M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e.

		Form 5 ii. Approval of product in Reference Regulatory Authorities is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
282.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	VERINE 135 mg Tablet
	Composition	Each Film Coated Tablet Contains; Mebeverine HCl…….. 135 mg
	Dairy No. date of R &I fee	Dy. No. 15310 dated 07.03.2019. Fee paid vide voucher No. 0835979 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Drugs For Functional Gastrointestinal DisordersSynthetic Anticholinergics, Esters With Tertiary Amino Group ATC Code: A03AA04
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Mebeverine hydrochloride 135mg Film-coated Tablets PL 21880/0250-252; UK/H/7036-37/001/DC MHRA Approved.
	Me-too-status	Spasfre Tablet 135mg Reg. No. 041750 M/s Himont Pharmaceuticals Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
283.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and trength	VISTA 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Rosuvastatin as calcium …. 10mg
	Dairy No. date of R &I fee	Dy. No. 15263 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0829577 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA07
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rosuvastatin DAWA 5,10, 20 and 40 mg Film-Coated Tablets MHRA Approved.
	Me-too-status	Hyporose 10mg tablet Reg. No. 050414 M/s Mediate Pharmaceutical (Pvt.) Ltd. Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5

	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
284.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VISTA 20mg Tablet
	Composition	Each Film Coated Tablet Contains; Rosuvastatin as calcium …. 20mg
	Dairy No. date of R &I fee	Dy. No. 15238 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0758994 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA07
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rosuvastatin DAWA 5,10, 20 and 40 mg Film-Coated Tablets MHRA Approved.
	Me-too-status	Hyporose 20mg tablet Reg. No. 050415 M/s Mediate Pharmaceutical (Pvt.) Ltd. Karachi
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
285.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEXET 60mg Tablet
	Composition	Each Tablet Contains; Fexofenadine HCl……..60mg
	Dairy No. date of R &I fee	Dy. No. 15342 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836435 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	)ther antihistamines for systemic use. ATC Code: R06AX26
	Type of form	Form-5A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LLEGRA 60mg Film-coated Tablets USFDA Approved.
	Me-too-status	Fexet Tablet 60mg Reg. No. 029434 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory**	

	authorities/agencies which were adopted by the Registration Board in its 275th meeting, or, • **Submission of revised formulation as per innovator product.**	
286.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEXET 120mg Tablet
	Composition	Each Tablet Contains; Fexofenadine HCl……..120mg
	Dairy No. date of R &I fee	Dy. No. 15341 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836434 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	)ther antihistamines for systemic use. ATC Code: R06AX26
	287. ype of form	Form-5A
	288. inished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fexofenadine Hydrochloride 120 mg and 180 mg Film-coated tablets PL 21880/0259-0260; UK/H/7053/002-003/DC MHRA Approved.
	Me-too-status	Fexet Tablet 120mg Reg. No. 029435 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or,** • **Submission of revised formulation and label as per innovator product.**	
289.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEXET 180mg Tablet
	Composition	Each Tablet Contains; Fexofenadine HCl……..180mg
	Dairy No. date of R &I fee	Dy. No. 15343 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0836436 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	)ther antihistamines for systemic use. ATC Code: R06AX26
	Type of form	Form-5A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fexofenadine Hydrochloride 120 mg and 180 mg Film-coated tablets PL 21880/0259-0260; UK/H/7053/002-003/DC MHRA Approved.

	Me-too-status	Fexet Tablet 180mg Reg. No. 029436 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of product in RRA as uncoated tablet could not be verified. Provide justification or change label claim along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or,** • **Submission of revised formulation and label claim as per innovator product.**	
290.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMENITEC 10 mg Tablet
	Composition	Each Tablet Contains Enalapril Maleate …… 5 mg
	Dairy No. date of R &I fee	Dy. No. 15291 dated 07.03.2019. Fee paid vide voucher No. 0835955 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE inhibitors, plain ATC Code: C09AA02
	Type of form	Form 5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO. As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Enalapril Maleate 5, 10, 20 mg Tablets (PL 44041/0012-0014) MHRA Approved
	Me-too-status	Cardiotec 20 mg Tablet Reg. No. 007706 M/s Wilsons Pharmaceuticals (Pvt.) Ltd. Islamabad
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
291.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMROFEC 75mg Tablet
	Composition	Each Film Coated Tablet Contains; Diclofenac Sodium …75mg
	Dairy No. date of R &I fee	Dy. No. 15301 dated 07.03.2019. Fee paid vide voucher No. 0835969 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Acetic acid derivatives and related substances. ATC Code: M01AB05
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	2x10's As per SRO.

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for strength of 75mg
	Me-too-status	)icmaf 75mg Tablet Reg. No. 092669 M/s Mafins Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Provide evidence of approval of product in RRA.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
292.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	GLIME 1.0 mg Tablet
	Composition	Each Film coated Tablet contains; Glimepiride …….. 1 mg
	Dairy No. date of R &I fee	Dy. No. 15273 dated 07.03.2019. Fee paid vide voucher No. 0829588 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Oral blood glucose lowering drugs: Sulfonamides, urea derivatives. ATC Code: A10BB12
	Type of form	Form 5-A
	Finished product specifications	Innovator Specifications
	Pack size and Demand Price	As per SRO and DRAP Policy.
	Approval status of product in Reference Regulatory Authorities	Glimepiride 1 mg Tablets MHRA Approved.
	Me-too-status	Amaryl tab 1 mg Reg. No. 019567 M/s Sanofi-Aventis Pakistan Ltd. Plot No. 23, Sector 22 Korangi Industrial Area Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Application shall be submitted on prescribed form i.e Form 5, currently Form 5-A is submitted. ii. Monograph of Glimepiride Tablets is present in pharmacopoeias; the firm shall revise specifications as per pharmacopoeia specifications. Submit requisite fee for the changes. iii. The product applied is a coated tablet, evidence of approval of coated tablet in RRA is required, or change label along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or submission of formulation and label claim as per innovator product.**	
293.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MLODI 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Amlodipine Besylate ……. 10 mg
	Dairy No. date of R &I fee	Dy. No. 15233 dated 07.03.2019. Fee paid vide voucher No. 0758797 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Dihydropyridine derivatives ATC Code: C08CA01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications

	Pack size and Demand Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities	Norvasc 10 mg Tablets (amlodipine besylate equivalent to 5 mg of amlodipine per tablet). FDA Approved
	Me-too-status	Norvasc Tablet 10mg Reg. No. 011826 M/s Pfizer Pakistan Ltd., B-2-SITE Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The specifications of the applied product are present in pharmacopoeia and specifications applied are mfg specifications. This needs correction along with requisite fee. iii. The product of innovator is not film coated and the applied product is film coated. Justification is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or submission of formulation and label claim as per innovator product.**	
294.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	CO-HARTAN 80mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains; Valsartan ……..80mg Hydrochlorothiazide …..12.5mg
	Dairy No. date of R &I fee	Dy. No. 15242 dated 07.03.2019. Fee paid vide voucher No. 0759000 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA03
	Type of form	Form-5A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan-Hydrochlorothiazide 80mg/12.5mg, 160mg/12.5mg and 160mg/25mg film-coated Tablets (valsartan and hydrochlorothiazide) -PL 43801/0031-0033. MHRA Approved.
	Me-too-status	Nuval-D 80/12.5mg Tablet Reg. No. 066838 M/s PharmEvo Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
295.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	CO-HARTAN 160mg/25mg Tablet
	Composition	Each Film Coated Tablet Contains; Valsartan ……..160mg Hydrochlorothiazide …..25mg

	Dairy No. date of R &I fee	Dy. No. 15280 dated 07.03.2019. Fee paid vide voucher No. 0829596 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA03
	Type of form	Form-5A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Valsartan-Hydrochlorothiazide 80mg/12.5mg, 160mg/12.5mg and 160mg/25mg film-coated Tablets (valsartan and hydrochlorothiazide) -PL 43801/0031-0033. MHRA Approved.
	Me-too-status	Nuval-D 160/25mg Tablet Reg. No. 066840 M/s PharmEvo Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
296.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	IRBES 150 mg Tablet
	Composition	Each Film Coated Tablet Contains; Irbesartan…….. 150 mg
	Dairy No. date of R &I fee	Dy. No. 15255 dated 07.03.2019. Fee paid vide voucher No. 0818380 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin-II Antagonists, Plain. ATC Code: C09CA04
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan 75 mg, 150 mg and 300 mg film-coated Tablets (irbesartan) PL 43801/0007-0009 MHRA Approved.
	Me-too-status	Irecon Tablet 150 mg Reg. No. 039726 M/s Barret Hodgson Pakistan Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
297.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	IRBES 300 mg Tablet
	Composition	Each film Coated Tablet Contains; Irbesartan…….. 300 mg
	Dairy No. date of R &I fee	Dy. No. 15251 dated 07.03.2019. Fee paid vide voucher No. 0818379 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin-II Antagonists, Plain. ATC Code: C09CA04
	Type of form	Form-5-A
	Finished product specifications	USP Specifications

	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan 75 mg, 150 mg and 300 mg film-coated Tablets (irbesartan) PL 43801/0007-0009 MHRA Approved.
	Me-too-status	Irecon Tablet 300 mg Reg. No. 039727 M/s Barret Hodgson Pakistan Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
298.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	CO-APRIL 5mg/25mg Tablet
	Composition	Each Film Coated Tablet Contains; Ramipril …….. 5mg Hydrochlorothiazide ….25mg
	Dairy No. date of R &I fee	Dy. No. 15358 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0835457 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE inhibitors and diuretics ATC Code: C09BA05
	Type of form	Form-5
	Finished product specifications	Manufacturers Specifications.
	Pack size and Demand Price	28's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ALTACE HCT Tablet DIN 02283174 Health Canada Approved.
	Me-too-status	Co-Triatec 5/25mg Tablet Reg. No. 043010 M/s Sanofi-Aventis Pakistan Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Specifications of Finished Product are mentioned as Manufacturers specifications.
	Decision: Approved with Innovator's Specifications.	
299.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	APRIL 2.5 mg Tablet
	Composition	Each Film Coated Tablet Contains; Ramipril…….. 2.5 mg
	Dairy No. date of R &I fee	Dy. No. 15227 dated 07.03.2019. Fee paid vide voucher No. 0758791 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ACE Inhibitors, plain, ATC Code: C09AA05
	Type of form	Form-5-A
	Finished product specifications	BP/USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Delix 2.5 Tablets (Hoescht MR, Germany) Bfarm Germany Approved
	Me-too-status	Tritace 2.5mg Tablets Reg. No. 019564 M/s Sanofi-Aventis Pakistan Ltd., Plot No. 23 Sector 22 Korangi Industrial Area Karachi

	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Evidence of coated tablet approval in RRA is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or submission of formulation and label claim as per innovator product.**	
300.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MEBIN 100 mg Tablet
	Composition	Each Film Coated Tablet Contains; Mebendazole ……. 100 mg
	Dairy No. date of R &I fee	Dy. No. 15365 dated 07.03.2019. Fee paid vide voucher No. 0836421 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	NTINEMATODAL AGENTS, Benzimidazole derivatives ATC Code: P02CA01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ERMOX 100 MG TABLETS MHRA Approved
	Me-too-status	Vermox 100 mg Reg. No. 004778 M/s Aspin Pharma (Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The strength of 500mg mebendazole is approved in RRA in chewable form, the applied product is not chewable. Clarification is required. iii. The applied product is film coated, and product approved in RRA is uncoated tablet. Clarification or revision is required along with submission of requisite fee.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or submission of formulation and label claim as per innovator product.**	
301.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	FORMIN 50mg/100mg Tablet
	Composition	Each Film Coated Tablet Contains; Vildagliptin …… 50mg Metformin HCl…….....1000mg
	Dairy No. date of R &I fee	Dy. No. 15253 dated 07.03.2019. Fee paid vide voucher No. 0818378 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ombinations of oral blood glucose lowering drugs. TC Code: A10BD08
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.

	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Vildagliptin/Metformin 50 mg/1000 mg Film-coated Tablets. MHRA Approved.
	Me-too-status	VildoMET 50mg/1000mg Tablet Reg. No. 073612 M/s High-Q Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
302.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMROFEC SR 100mg Tablet
	Composition	Each Enteric Coated Tablet Contains; Diclofenac Sodium……..100mg
	Dairy No. date of R &I fee	Dy. No. 15302 dated 07.03.2019. Fee paid vide voucher No. 0835970 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS. ATC Code: M01AB05
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	2x10's. AS per SRO.
	Approval status of product in Reference Regulatory Authorities	DICLOFENAC SODIUM, 100MG, TABLET, EXTENDED RELEASE; ORAL USFDA Approved.
	Me-too-status	Hirun SR 100mg Tablet Reg. No. 094963 M/s Hilton Pharma (Pvt) Ltd Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The product name is of sustained release product, formulation and label claim is of enteric coated tablet. The reference in RRA is of Extended Release tablet not of enteric coated. Justifications or corrections are required in label claim and formulation along with submission of requisite fee(Full Fee).
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or submission of formulation and label claim as per innovator product.**	
303.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	P-N Tablet 5mg
	Composition	Each Tablet Contains; Norethisterone……..5mg
	Dairy No. date of R &I fee	Dy. No. 15304 dated 07.03.2019. Fee paid vide voucher No. 0835972 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Progestogens, Estrane derivatives.

		ATC Code: G03DC02
	Type of form	Form-5
	Finished product specifications	
	Pack size and Demand Price	3x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Norethisterone 5mg Tablets PL 29831/0152 MHRA Approved.
	Me-too-status	Noregyn 5mg Tablet Reg. No. 053336 M/s Zafa Pharmaceutical Lab Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	Finished product specifications are not mentioned.
	Decision: Deferred for confirmation of manufacturing facility.	
304.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VASTCOR 20mg Tablet
	Composition	Each Film Coated Tablet Contains; Simvastatin…….. 20mg
	Dairy No. date of R &I fee	Dy. No. 15294 dated 07.03.2019. Fee paid vide voucher No. 0835961 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Simvastatin 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets PL 49565/0014-0017 MHRA Approved.
	Me-too-status	Simvoget Tabl;et 20mg Reg. No. 044047 M/s Getz Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
305.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	AMBROBION Tablet
	Composition	Each Tablet Contains; Thiamine Disulphide (Vitamin B1) ……. 100mg Pyridoxine Hydrochloride (Vitamin B6)…200mg Cyanocobalamine (Vitamin B12)……..200mcg
	Dairy No. date of R &I fee	Dy. No. 15299 dated 07.03.2019. Fee paid vide voucher No. 0835967 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Vitamin B1 in combination with vitamin B6 and/or vitamin B12. ATC Code: A11DB
	Type of form	Form-5-A
	Finished product specifications	
	Pack size and Demand Price	10x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too-status	Neurobion Tablet Reg. No. 001486 M/s Martin Dow Ltd. Karachi.

	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 Finished Product Specifications are not mentioned. Approval in RRA could not be verified.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
306.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	ZINEDAL 10mg Tablet
	Composition	Each Film Coated Tablet Contains; Cetirizine dihydrochloride……5mg
	Dairy No. date of R &I fee	Dy. No. 15229 dated 07.03.2019. Fee paid vide voucher No. 0758793 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE, Piperazine derivatives ATC Code: R06AE07
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cetirizine dihydrochloride 10 mg film-coated tablets (cetirizine dihydrochloride) - PL 20416/0278 MHRA Approved.
	Me-too-status	Rigix 10mg Tablet Reg. No. 011248 M/s AGP Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
307.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	CANDEN PLUS Tablet 16mg/12.5mg
	Composition	Each Film Coated Tablet Contains; Candesartan Cilexetil …….16mg Hydrochlorothiazide …..12.5mg
	Dairy No. date of R &I fee	Dy. No. 15261 dated 07.03.2019. Fee paid vide voucher No. 0829575 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC code: C09DA06
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Candesartan and Hydrochlorothiazide 8/12.5, 16/12.5, 32/25 & 32/12.5 mg Tablets - PL 20416/0343-46. MHRA Approved.
	Me-too-status	Prosartan-DU 16/12.5 tablets Reg. No. 055826 M/s Helix Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.

	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 The product applied is a film coated product. Product approved in RRA is an uncoated tablet. Clarification or correction is required along with submission of requisite fee. Product monograph is available in USP and innovator's specifications are applied. Justification or correction is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Revision of Specifications.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, or submission of formulation and label claim as per innovator product.**	
308.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	COXIB 200mg Capsule
	Composition	Each Capsule Contains; Celecoxib …….200mg
	Dairy No. date of R &I fee	Dy. No. 15235 dated 07.03.2019. Fee paid vide voucher No. 0758799 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Coxibs. ATC Code: M01AH01
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Celecoxib 100 mg capsules, hard and Celecoxib 200 mg capsules, hard (celecoxib) - PL 35507/0133 -0134 MHRA Approved.
	Me-too-status	Colixib Capsule 200mg Reg. No. 100505 M/s High-Q Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
309.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	XAMIC 250mg Capsules
	Composition	Each Capsule Contains; Tranexamic Acid ……..250mg
	Dairy No. date of R &I fee	Dy. No. 15297 dated 07.03.2019. Fee paid vide voucher No. 0835965 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	2x10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for capsule dosage form.
	Me-too-status	Haemic Capsule 250mg Reg. No. 039014 M/s Genix Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate

		valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 Provide evidence of RRA approval of product in Capsule dosage form.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
310.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Capsule Section (General)
	Brand Name + Dosage Form and Strength	XAMIC 500mg Capsules
	Composition	Each Capsule Contains; Tranexamic Acid ……..500mg
	Dairy No. date of R &I fee	Dy. No. 15296 dated 07.03.2019. Fee paid vide voucher No. 0835964 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	2x10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for capsule dosage form.
	Me-too-status	Haemic Capsule 500mg Reg. No. 039016 M/s Genix Pharma Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 Evidence of RRA approval of product in Capsule dosage form is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
311.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MEPRA 20mg Capsule
	Composition	Each Capsule Contains; Esomeprazole Magnesium trihydrate eq. Esomeprazole 22.5% pellets …20mg
	Dairy No. date of R &I fee	Dy. No. 15282 dated 07.03.2019. Fee paid Rs. 80,000/- vide voucher No. 0836445 dated 05.03.2019, endorsed on 07.03.2019 Fee paid Rs. 20,000/- vide voucher No. 0752860 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Esomeprazole 20mg Gastro-resistant Capsules (esomeprazole magnesium dihydrate) - PL 16028/0166. MHRA Approved.

	Me-too-status	Nexum 20mg Capsule Reg. No. 033890 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Source of pellets is required. ii. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of source of pellets.**	
312.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MEPRA 40mg Capsule
	Composition	Each Capsule Contains; Esomeprazole Magnesium trihydrate eq. Esomeprazole 22.5% pellets …40mg
	Dairy No. date of R &I fee	Dy. No. 15239 dated 07.03.2019. Fee paid Rs. 80,000/- vide voucher No. 0836446 dated 05.03.2019, endorsed on 07.03.2019 Fee paid Rs. 20,000/- vide voucher No. 0758995 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT CAPSULES HARD. MHRA Approved.
	Me-too-status	Nexum 40mg Capsule Reg. No. 033891 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Source of pellets is required. ii. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of source of pellets.**	
313.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Cream/Ointment Section (General)
	Brand Name + Dosage Form and Strength	NITRA 20mg/g Oral Gel
	Composition	Not provided
	Dairy No. date of R &I fee	Dy. No. 15344 dated 07.03.2019. Fee paid vide voucher No. 0836437 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antiinfectives and antiseptics for local oral treatment. ATC Code: A01AB09
	Type of form	Form-5-A
	Finished product specifications	BP Specifications
	Pack size and Demand Price	10g, 20g. As per SRO.
	Approval status of product in Reference Regulatory Authorities	DAKTARIN ORAL GEL miconazole 20mg/g gel tube. TGA Australia Approved.

	Me-too-status	DAKTARIN Oral gel 20mg Reg. No. 009078 M/s Aspin Pharma(Pvt) Ltd. Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Label claim of Next Tablet is given instead of applied product (page 98). Label Claim of applied product is required. Also submit fee for revision of label along with fee (Full Fee) iii. The gel formulation approved in RRA is an oral gel, the applied product's intended clinical use is not as an oral gel. The Me-too Gel formulations are also oral gels. Evidence of gel for non-oral use approved in RRA is required and also its me-too.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of formulation and proper label.** • **Submission of proper label claim and intended use of product.** • **Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.**	
314.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Cream/ointment Section (General)
	Brand Name + Dosage Form and Strength	AMCIN-V 2% Vaginal Cream
	Composition	
	Dairy No. date of R &I fee	Dy. No. 15331 dated 07.03.2019. Fee paid vide voucher No. 0836000 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS, Antibiotics. ATC Code: G01AA10
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10g, 20g, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dalacin Cream 2% (Vaginal Cream) MHRA approved.
	Me-too-status	Femcin-V 2% Cream Reg. No. 101644 M/s Evolution Pharma Rawat.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 Label claim of GABA Tablet is given instead of applied product (page 103). Label claim of applied product is required. Also submit fee for revision of label claim (Full Fee)
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of formulation and proper label.** • **Submission of proper label claim and intended use of product.** • **Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.**	
315.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Cream/ointment Section (General)

	Brand Name + Dosage Form and Strength	BETASOL OINTMENT 0.05%
	Composition	Each gram of Ointment contains; Clobetasol Propionate……0.05mg (0.05% W/W)
	Dairy No. date of R &I fee	Dy. No. 15356 dated 07.03.2019. Fee paid vide voucher No. 0836443 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Corticosteroids, very potent (group IV). ATC Code: D07AD01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Clobetasol Propionate 0.05% w/w Ointment (PL17507/00236) MHRA Approved.
	Me-too-status	Clobetol ointment 0.05% Reg. No. 065177 M/s Valor Pharmaceuticals Islamabad
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The label claim needs to be corrected as percentage strength is different from per gram strength. Also submit requisite fee for revision of label claim (Full fee)
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of revised label and formulation as per innovator product.**	
316.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Tablet Section (General)
	Brand Name + Dosage Form and Strength	BETASOL CREAM 0.05%
	Composition	Each gram of Cream Contains; Clobetasol propionate……..0.05mg(0.05% W/W)
	Dairy No. date of R &I fee	Dy. No. 15348 dated 07.03.2019. Fee paid vide voucher No. 0836441 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Corticosteroids, very potent (group IV). ATC Code: D07AD01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Clobetasol Propionate 0.05% w/w Cream (PL 17507/0235) MHRA Approved.
	Me-too-status	Clobicare Cream 0.05% Reg. No. 067938 M/s Seatle Pharma Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. The label claim needs to be corrected as percentage strength is different from per gram strength. Also submit requisite fee for revision of label claim (Full fee)
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of revised label and formulation as per innovator product.**	

317.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	MEBIN 100mg/5ml Oral Suspension
	Composition	Each 5ml Suspension Contains; Mebendazole ……..100mg
	Dairy No. date of R &I fee	Dy. No. 15375 dated 07.03.2019. Fee paid vide voucher No. 0836444 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTINEMATODAL AGENTS, Benzimidazole derivatives. ATC Code: P02CA01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VERMOX 100 MG/5 ML ORAL SUSPENSION MHRA Approved.
	Me-too-status	Nemazole Suspension Reg. No. 013321 M/s GSK Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
318.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Oral Liquid Section (General)
	Brand Name + Dosage Form and Strength	NILSIT Oral DROPS 100,000IU/ml
	Composition	Each ml Contains; Nystatin ……100,000IU
	Dairy No. date of R &I fee	Dy. No. 15305 dated 07.03.2019. Fee paid vide voucher No. 0835973 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	INTESTINAL ANTIINFECTIVES, Antibiotics. ATC Code: A07AA02
	Type of form	Form-5
	Finished product specifications	
	Pack size and Demand Price	30ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	NYSTATIN ORAL SUSPENSION BP MHRA Approved.
	Me-too-status	Nilstat Drops Reg. No. 001554 M/s ICI Pakistan Hattar.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. It is not mentioned what will be the specifications of Finished Product.
	Decision: Deferred for submission of correct Form-5 along with full fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
319.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ANZAL 600mg/300ml Infusion
	Composition	Each 100ml Contains; Linezolid…….200mg
	Dairy No. date of R &I fee	Dy. No. 15319 dated 07.03.2019. Fee paid vide voucher No. 0835988 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antibacterials

		ATC Code: J01XX08
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Linezolid 2 mg/ml Solution for Infusion - PL 36780/0001; UK/H/5511/001/DC Each infusion bag contains 300 ml of Linezolid 2mg/ml Infusion. MHRA Approved.
	Me-too-status	Nezkil 600mg Infusion Reg. No. 048804 M/s SJ&Fazul Ellahi Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Section approval letter is required along with evidence that LVP manufacturing facility is present. iii. Label claim given at page 121 mentions that each 100ml contains 600mg/300ml. The label claim needs to be corrected along with submission of requisite fee (Full fee)
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of proper label claim and formulation.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of LVP Section/manufacturing facaility.**	
320.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ANZAL 200mg/100ml Infusion
	Composition	Each 100ml Contains; Linezolid…….200mg
	Dairy No. date of R &I fee	Dy. No. 15318 dated 07.03.2019. Fee paid vide voucher No. 0835987 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antibacterials ATC Code: J01XX08
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	LINEZOLID, 200MG/100ML (2MG/ML), SOLUTION; INTRAVENOUS. USFDA Approved.
	Me-too-status	Nezkil 200mg Infusion Reg. No. 048802 M/s SJ&Fazul Ellahi Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Section approval letter is required along with evidence that LVP manufacturing facility is present.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of LVP Section/manufacturing facaility.**	

321.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	VENTO 0.5mg/1ml Injection
	Composition	Each 1ml Ampoule Contains; Albuterol Sulfate …..0.5mg
	Dairy No. date of R &I fee	Dy. No. 15336 dated 07.03.2019. Fee paid vide voucher No. 0836429 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists ATC Code: R03CC02
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ventolin 500mcg/ml Injection (1ml glass ampoule) MHRA Approved.
	Me-too-status	Ventolin Injection Reg. No. 005904 M/s GSK Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. It is not mentioned that whether product will be an ampoule or a vial. And also volume of injection is not mentioned. iii. The route of administration is mentioned as oral.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of details of product including formulation, label claim and intended use.**	
322.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ZEEN 10mg/ml Injection IV/IM
	Composition	Each 1ml Ampoule Contains; Nalbuphine HCl……10mg
	Dairy No. date of R &I fee	Dy. No. 15240 dated 07.03.2019. Fee paid vide voucher No. 0758996 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	OPIOIDS, Morphinan derivatives. ATC Code: N02AF02
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified as container and volume is not mentioned.
	Me-too-status	Bunail Injection 10mg/ml Reg. No. 053437 M/s Bosch Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Dosage Form is mentioned as film coated tablet. iii. Route of Administration is mentioned as oral iv. Evidence of approval of product in RRA could not be verified. Proper Evidence of approval of

		product having similar volume and container in RRA is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of proper details of the applied product including label claim, formulation and intended use.**	
323.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	ZEEN 20mg/ml Injection IV/IM
	Composition	Each 1ml Ampoule Contains; Nalbuphine HCl…….20mg
	Dairy No. date of R &I fee	Dy. No. 15231 dated 07.03.2019. Fee paid vide voucher No. 0758795 dated 02.03.2019, endorsed on 07.03.2019
	Pharmacological Group	OPIOIDS, Morphinan derivatives. ATC Code: N02AF02
	Type of form	Form-5-A
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified as container and volume is not mentioned.
	Me-too-status	Bunail Injection 20mg/ml Reg. No. 053438 M/s Bosch Pharmaceuticals Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Dosage Form is mentioned as film coated tablet. iii. Route of Administration is mentioned as oral iv. Evidence of approval of product in RRA could not be verified. Proper Evidence of approval of product having similar volume and container in RRA is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of proper details of the applied product including label claim, formulation and intended use.**	
324.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	AMCIN-C Injection 150mg/ml
	Composition	Each 1ml Ampoule Contains; Clindamycin as Phosphate …..150mg
	Dairy No. date of R &I fee	Dy. No. 15328 dated 07.03.2019. Fee paid vide voucher No. 0835997 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, Lincosamides.

		ATC Code: J01FF01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	CLINDAMYCIN 150MG/ML SOLUTION FOR INJECTION PL 24780/0002 2ml and 4ml ampoules MHRA Approved.
	Me-too-status	Dalacin C Injection Reg. No. 004592 M/s Pfizer Pakistan Karachi.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. It is not mentioned whether product will be an ampoule or vial, neither volume is mentioned. The strength, volume and container should be as that of innovator, for revision submit requisite fee (Full Fee.)
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of proper details of the applied product including label claim, formulation and intended use.**	
325.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	AMCIN-C Injection 300mg/ml
	Composition	Each 1ml Ampoule Contains; Clindamycin as Phosphate …..300mg
	Dairy No. date of R &I fee	Dy. No. 15326 dated 07.03.2019. Fee paid vide voucher No. 0835995 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, Lincosamides. ATC Code: J01FF01
	Type of form	Form-5-A
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too-status	Could not be verified.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. It is not mentioned whether product will be an ampoule or vial, neither volume is mentioned. iii. Evidence of product approval in RRA is required. iv. Evidence of me-too is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of details of applied product i.e. formulation, label, container closure system etc.**	

326.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	DECADON INJECTION 8mg/2ml (IV/IM)
	Composition	Each 2ml Vial Contains; Dexamethasone Sodium Phosphate Eq. to Dexamethasone Phosphate ……8mg
	Dairy No. date of R &I fee	Dy. No. 15334 dated 07.03.2019. Fee paid vide voucher No. 0836412 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Glucocorticoids ATC Code: H02AB02
	Type of form	Form-5
	Finished product specifications	Not mentioned.
	Pack size and Demand Price	2ml Vial. As per SRO.
	Approval status of product in Reference Regulatory Authorities	DEXAMETHASONE 8.3 MG/ML SOLUTION FOR INJECTION - PL 01502/0081 MHRA Approved.
	Me-too-status	Could not be verified.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Specifications of Finished product are not mentioned. ii. Provide Me-too of the applied product. iii. Provide evidence of RRA approval of the applied product.
	Decision: Deferred for following; • **Submission of specifications of the finished product.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of approval of required manufacturing facility of "Liquid Injecatble (Steroid)" Section from CLB.**	
327.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injection Section (General)
	Brand Name + Dosage Form and Strength	XAMIX 250mg/5ml Injection
	Composition	Each 5ml Injection Contains; Tranexamic Acid……..250mg
	Dairy No. date of R &I fee	Dy. No. 15295 dated 07.03.2019. Fee paid vide voucher No. 0835963 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIFIBRINOLYTICS, Amino acids ATC Code: B02AA02
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	2x10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified for strength of 250mg
	Me-too-status	Transamin Injection 250mg Reg. No. 007534
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Route of administration is mentioned as Oral.

		iii. It is not mentioned whether injection will be a vial or an ampoule. Volume of injection is also not mentioned in the label claim. Mention volume of injection along with submission of requisite fee (Full Fee) iv. Evidence of approval of the product in RRA having applied strength is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of intended route of administration of applied product.** • **Submission of details of applied product i.e. label, formulation, container closure system etc.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
328.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Injectable Section (General)
	Brand Name + Dosage Form and Strength	AMROKET 30mg/3ml Injection (IM/IV) (For toll manufacturing)
	Composition	Each 3ml Ampoule Contains; Ketorolac Tromethamine……..30mg
	Dairy No. date of R &I fee	Dy. No. 15372 dated 07.03.2019. Fee paid vide voucher No. 0836426 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Acetic acid derivatives and related substances. ATC Code: M01AB15
	Type of form	Form-5-A
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	1x1 As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/ml Solution for Injection MHRA Approved
	Me-too-status	Toralac Injection 30mg Reg. No. 050290 M/s Global Pharma Islamabad.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i.The application is submitted on Form-5A. Application shall be submitted on correct form i.e. Form 5 ii. Contract manufacturing details are not provided and on application form Toll manufacturing is mentioned. iii. Volume of ampoule is not mentioned. It needs to be defined along with submission of requisite fee (Full Fee).
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Submission of details of applied product i.e. formulation, label, container closure system etc.** • **Submission of clarification why contract manufacturing is mentioned in the application.**	
329.	Name and address of manufacture / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi (DML No. 000406) Ear/Eye Drop Section (General)
	Brand Name + Dosage Form and Strength	GENTAMYCIN HC DROPS 0.3%/1%
	Composition	Each 100ml Contains; Gentamycin Sulphate eq. to Base…… 0.3%W/V Hydrocortisone Acetate……..1.0% W/V
	Dairy No. date of R &I fee	Dy. No. 15355 dated 07.03.2019. Fee paid vide voucher No. 0836413 dated 05.03.2019, endorsed on 07.03.2019

	Pharmacological Group	Corticosteroids and antiinfectives in combination. ATC Code: S03CA04
	Type of form	Form-5-A
	Finished product specifications	Not mentioned.
	Pack size and Demand Price	5ml. as per SRO
	Approval status of product in Reference Regulatory Authorities	GENTAMICIN 0.3% W/V AND HYDROCORTISONE ACETATE 1% W/V EAR DROPS, GENTISONE HC EAR DROPS MHRA Approved.
	Me-too-status	Otogen HC Ear Drops Reg. No. 016662 M/s Remington Pharmaceuticals Lahore.
	GMP Status	Inspection report 28.10.2022 is submitted. GMP certificate valid till 27.10.2024 is submitted.
	Remark of the Evaluator.	i. Specifications of finished product are not defined. ii. Pack size if of 5 ml and label claim is made of 100ml, justification or correction is required along with submission of requisite fee. iii. The pack size of RRA approved product is 10ml, justification for applied pack size is required.
	Decision: Deferred for following; • **Submission of correct Form-5 along with full fee.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of specifications of the applied product.**	
330.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VERTOCIN Tablet 16mg
	Composition	Each tablet contains: Betahistine Dihydrochloride ……. 16mg
	Dairy No. date of R &I fee	Dy. No. 14829 dated 07-03-2019 Rs.20,000/- dated 06-03-2019 Challan No. 0760161.
	Pharmacological Group	ANTIVERTIGO PREPARATIONS ATC Code: N07CA01
	Type of form	Form 5
	Finished product specifications	BP specifications
	Pack size and Demand Price	30's, as per SRO
	Approval status of product in Reference Regulatory Authorities	Betahistine Dihydrochloride 16mg Tablets, MHRA Approved
	Me-too-status	BHS Tablet 16mg, Rotex Pharma, Reg. No. 100819
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved	
331.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VERTOCIN Tablet 8 mg
	Composition	Each tablet contains: Betahistine Dihydrochloride …….. 8 mg
	Dairy No. date of R &I fee	Dy. No. 14828 dated 07-03-2019 Rs.20,000/- dated 06-03-2019 Challan No. 0760160.

	Pharmacological Group	N07C ANTIVERTIGO PREPARATIONS
	Type of form	Form 5
	Finished product specifications	BP specifications
	Pack size and Demand Price	30's, as per SRO
	Approval status of product in Reference Regulatory Authorities	Betahistine Dihydrochloride 8mg Tablets, MHRA Approved
	Me-too-status	BHS Tablet 8mg, Rotex Pharma, Reg. No. 100819
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved	
332.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	NEOGLIP 2.5mg Tablet
	Composition	Each Film Coated Tablet contains; Saxagliptin HCl (Anhydrous) Eq. to Saxagliptin ……..2.5 mg
	Dairy No. date of R &I fee	Dy. No. 14842 dated 07-03-2019, Rs. 20,000/- dated 06.03.2019. Challan No. 0760174
	Pharmacological Group	Drugs used in diabetes. Dipeptidyl peptidase 4 (DPP4) inhibitors, ATC code: A10BH03
	Type of form	Form 5
	Finished product specifications	ARP Specs
	Pack size and Demand Price	10's, as per SRO
	Approval status of product in Reference Regulatory Authorities	Onglyza 2.5 mg film-coated tablets Each tablet contains 2.5 mg saxagliptin (as hydrochloride). MHRA Approved
	Me-too-status	Saglip 2.5mg Tablet Reg. No. 071487. Mfg by M/s CCL Lahore.
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	i. The Pharmacological group of the drug mentioned in the application is Psychotropic agent. The ATC for drug Saxagliptin is A10B defined as BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS. Also submit requisite fee. ii. The manufacturing method provided mentions that the tablet will be manufactured by simple compression having active in the compressed core, then it will be film coated. The manufacturing method of the innovator is through active coating process. The revised manufacturing method is required to be submitted along with supplementary data. Also submit requisite fee. The firm has submitted the revised Form-5 and revised manufacturing method as per innovator product, along with fee of Rs. 7500/- paid vide slip No. 54293912720 dated 23.09.2022.
	Decision: Deferred for following; • **Submission of detailed manufacturing method as per innovator product along with evidence of required equipment for manufacturing it.** • **Submission of evidence that manufacturing process will prevent cyclization of the API.** • **Submission of stability study data as per guidelines provided in 293rd meeting of**	

	Registration Board.	
333.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	VORIFEN 200mg Tablet
	Composition	Each Film coated tablet contains; Voriconazole…… 200 mg
	Dairy No. date of R &I fee	Dy. No. 14831, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760163
	Pharmacological Group	Antimycotics for systemic use, triazole derivatives ATC code J02AC03
	Type of form	Form 5
	Finished product specifications	JP Specifications.
	Pack size and Demand Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	VFEND Voriconazole 200 mg Oral Tablet USFDA Approved.
	Me-too-status	Vorif Tablet 200mg Reg. No. 069765. Mfg by M/s Ferozsons Laboratories Ltd., Amangarh Nowshehra, Nowshera.
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
334.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	ISOVEN ER Tablet 50mg
	Composition	Each Extended Release Tablet Contains; Desvenlafaxine (as succinate)…… 50 mg
	Dairy No. date of R &I fee	Dy. No. 14834, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760182
	Pharmacological Group	Other Antidepressants. ATC Code: N06AX23
	Type of form	Form 5
	Finished product specifications	ARP Specifications
	Pack size and Demand Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Pristiq (desvenlafaxine) Extended-Release tablets, oral USFDA Approved.
	Me-too-status	Dessyn XR 50mg Tablet, Reg. No. 091609. M/s Medisynth Pharmaceuticals Rawat.
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved with innovator's Specifications. Registration letter shall be issued after submission of fee Rs. 7500/- for revision of specifications.	
335.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	ISOVEN ER Tablet 100mg
	Composition	Each Extended Release Tablet Contains; Desvenlafaxine (as succinate)…… 100 mg
	Dairy No. date of R &I fee	Dy. No. 14835, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760183
	Pharmacological Group	Other Antidepressants. ATC Code: N06AX23

	Type of form	Form 5
	Finished product specifications	ARP Specifications
	Pack size and Demand Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Pristiq (desvenlafaxine) Extended-Release tablets, oral USFDA Approved.
	Me-too-status	Dessyn XR 100mg Tablet, Reg. No. 091610. M/s Medisynth Pharmaceuticals Rawat.
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved with innovator's Specifications. Registration letter shall be issued after submission of fee Rs. 7500/- for revision of specifications.	
336.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Capsule Section (General)
	Brand Name + Dosage Form and Strength	MUSOREL MR 200 mg Capsule.
	Composition	Each MR capsule contains (Modified Release); Mebeverine HCl SR 50% Pellets Eq. to Mebeverine HCl ……. 200mg (source of Pellets: M/s Vision Pharmaceuticals Islamabad DML No. 000806)
	Dairy No. date of R &I fee	Dy. No. 14840, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760184
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group. ATC Code: A03AA04
	Type of form	Form 5
	Finished product specifications	ARP Specifications
	Pack size and Demand Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	COLOFAC MR Modified Release Capsule Mebeverine hydrochloride 200 mg Manufactured by Mylan Products Ltd. 20 Station Close Potters Bar Herts EN6 1TL United Kingdom. MHRA Approved.
	Me-too-status	Mebever MR 200mg Capsule Reg. No. 050747 M/s Getz Pharma Karachi.
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved with innovator's Specifications. Registration letter shall be issued after submission of fee Rs. 7500/- for revision of specifications.	
337.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Q-REX Tablet 100 mg
	Composition	Each Film Coated Tablet Contains; Quetiapine (as Fumarate) ……. 100 mg
	Dairy No. date of R &I fee	Dy. No. 14844, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760176
	Pharmacological Group	Antipsychotics; Diazepines, oxazepines and thiazepines ATC code: N05AH04
	Type of form	Form 5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10's, 20's, 30's. As per SRO.

	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg, 100mg, 150mg, 200mg) by M/s Aurobindo pharma, MHRA Approved.
	Me-too-status	Quepin 100mg Tablet Reg. No. 055644 M/s Platinum Pharmaceuticals (Pvt.) Ltd., Karachi
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant..
	Remark of the Evaluator.	
	Decision: Approved.	
338.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Q-REX XR Tablet 300 mg
	Composition	Each Extended Release Tablet Contains; Quetiapine (as Fumarate) …… 300 mg
	Dairy No. date of R &I fee	Dy. No. 14846, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760186
	Pharmacological Group	Antipsychotics; Diazepines, oxazepines and thiazepines ATC code: N05AH04
	Type of form	Form 5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SEROQUEL XR (quetiapine fumarate) Extended-Release Tablets 200 mg, 300 mg, and 400 mg M/s AstraZeneca Pharmaceuticals LP 36 Wilmington, DE 19850 USA FDA Approved.
	Me-too-status	Pequit XR 300mg Tablets Reg. No. 075488 Each XR coated Tablet contains; Quetiapine (as fumarate): 300mg M/s Medizan Laboratories (Pvt) Ltd., Plot No 313 Industrial Triangle Kahuta Road Islamabad., Islamabad
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
339.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Q-REX XR Tablet 150 mg
	Composition	Each Extended Release Tablet contains; Quetiapine (as fumarate) ……. 150 mg
	Dairy No. date of R &I fee	Dy. No. 14845, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760185
	Pharmacological Group	Antipsychotics; Diazepines, oxazepines and thiazepines ATC code: N05AH04
	Type of form	Form 5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel XL 50 mg, 150 mg, 200 mg, 300 mg, 400 mg prolonged-release tablets AstraZeneca UK Ltd, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, United Kingdom MHRA Approved.

	Me-too-status	Pequit XR 150mg Tablets Reg. No. 075486 Each XR coated Tablet contains; Quetiapine (as fumarate): 150 mg M/s Medizan Laboratories (Pvt) Ltd., Plot No 313 Industrial Triangle Kahuta Road Islamabad., Islamabad.
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
340.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Q-REX Tablet 25 mg
	Composition	Each Film Coated Tablet contains; Quetiapine (as fumarate) ……. 25 mg
	Dairy No. date of R &I fee	Dy. No. 14843, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760175
	Pharmacological Group	Antipsychotics; Diazepines, oxazepines and thiazepines ATC code: N05AH04
	Type of form	Form 5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10's 20's 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel 25 mg, 100 mg, 200 mg and 300 mg film-coated tablets MHRA Approved.
	Me-too-status	Quepin 25mg Tablet Reg. No. 055643 M/s PlatinumPharmaceuticals(Pvt.) Ltd., Karachi
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
341.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	MESOBAC Tablet 10 mg
	Composition	Each Tablet Contains; Baclofen ……. 10 mg
	Dairy No. date of R &I fee	Dy. No. 14836, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760168
	Pharmacological Group	Muscle relaxants, centrally acting agents, Other centrally acting agents ATC Code: M03BX01
	Type of form	Form 5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Baclofen 10 mg Tablets M/s TEVA UK Limited, Eastbourne, BN22 9AG, UK MHRA Approved.
	Me-too-status	Baclin Tablet Reg. No. 063100 Baclofen……..10mg M/s Genome Pharmaceuticals (Pvt) Ltd., Plot No.16/1 Phase No. IV Industrial Estate Hattar Distt Haripur., Haripur
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.

	Remark of the Evaluator.	
	Decision: Approved.	
342.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	PROQUAD Tablet 150mg/75mg/400mg/275mg
	Composition	Each Film Coated Tablet Tablet Contains; Rifampicin …….. 150 mg Isoniazide ……. 75 mg Pyrazinamide ……..... 400 mg Ethambutol Hydrochloride ….. 275 mg
	Dairy No. date of R &I fee	Dy. No. 14833, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760165
	Pharmacological Group	Combinations of drugs for treatment of tuberculosis (rifampicin, pyrazinamide, ethambutol and isoniazid). ATC Code: J04AM06
	Type of form	Form-5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	80's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Rimstar 150 mg/75 mg/400 mg/275 mg Film-coated Tablets M/s Sandoz Limited Park View, Riverside Way Watchmoor Park Camberley, Surrey GU15 3YL United Kingdom MHRA Approved.
	Me-too-status	Myrin P Forte Tablets Reg. No. 027082 M/s Pfizer Pakistan Ltd., B-2-SITE Karachi.
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
343.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	FUNOKET 200 mg Tablet
	Composition	Each Tablet Contains; Ketoconazole ……..200mg
	Dairy No. date of R &I fee	Dy. No. 14837, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760169
	Pharmacological Group	CORTICOSTEROIDS FOR SYSTEMIC USE, Anticorticosteroids ATC Code: H02CA03
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketoconazole HRA 200 mg tablets MHRA Approved.
	Me-too-status	KZ 200mg Tablet Reg. No. 092348 M/s Seraph Pharmaceutical, Plot No.210, Industrial Triangle, Kahuta Road, Islamabad
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	The Pharmacological group mentioned in application is "broad-spectrum synthetic antifungal agent". The pharmacotherapeutic group of the reference product (i.e.

		Ketoconazole HRA 200mg tablet) is Corticosteroids for systemic use, Anticorticosteroids ATC Code: H02CA03. Evidence of pharmacological group along with supporting data is required or Pharmacological group may be revised along with submission of requisite fee. The firm has provided the requisite information along with submission of fee Rs. 7500/- vide Slip No. 1861017220 dated 23.09.2022.
	Decision: Approved.	
344.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	ZEEMIG Tablet 5 mg
	Composition	Each Film Coated Tablet Contains; Zolmitriptan ……. 5 mg
	Dairy No. date of R &I fee	Dy. No. 14849, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760181
	Pharmacological Group	ANTIMIGRAINE PREPARATIONS, Selective serotonin (5HT1) agonists ATC Code: N02CC03
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	3's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Zolmitriptan 5mg Film-coated Tablets M/s Accord, Barnstaple, EX32 8NS, UK MHRA Approved
	Me-too-status	Zolon Tablet Reg. No. 088749 M/s Shrooq Pharmaceuticals (Pvt) Ltd , 21-Km Ferozepur Road, Lahore
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
345.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	BUSPORIL Tablet 5 mg
	Composition	Each Tablet Contains; Buspirone Hydrochloride …….. 5 mg
	Dairy No. date of R &I fee	Dy. No. 14832, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760164
	Pharmacological Group	Anxiolytics, Azaspirodecanedione Derivatives. ATC Code: N05BE01
	Type of form	Form-5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Buspar Tablets 5 mg M/s Accord Healthcare Limited Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom. MHRA Approved
	Me-too-status	Buspro Tablet 5mg Reg. No. 094261 M/s Medisynth Pharmaceuticals, Plot No. 55 Street No. S-5 National Industrial Zone Rawat.

	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
346.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Tablet Section (General)
	Brand Name + Dosage Form and Strength	RENAID Tablet
	Composition	Each Film Coated Tablet Contains; α-keto analogue to isoleucine calcium salt …. 67 mg α-keto analogue to leucine calcium salt …. …101 mg α-keto analogue to phenylalanine calcium salt . 68 mg α-keto analogue to valine calcium salt …. 86 mg α-hydroxy analogue to methionine calcium salt 59 mg Lysine acetate ……. 105 mg L-threonine …….. 53 mg L-tryptophan …… 23 mg L- histidine …….. 38 mg L- tyrosine …… 30 mg Total Nitrogen content per tablet …….. 36 mg Calcium content per tablet …1.25 mmol = 50 mg
	Dairy No. date of R &I fee	Dy. No. 14830, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760162
	Pharmacological Group	GENERAL NUTRIENTS, OTHER NUTRIENTS Amino acids, incl. combinations with polypeptides ATC Code: V06DD
	Type of form	Form-5
	Finished product specifications	ARP Specifications.
	Pack size and Demand Price	100's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	KETOSTERIL by Fresenius Kabi, Germany. (Bfarm approved)
	Me-too-status	Ketoalfa Tablets Reg. No. 076807 M/s Genome Pharmaceuticals (Pvt) Ltd., Plot No.16/1 Phase No. IV Industrial Estate Hattar Distt Haripur
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Deferred for evidence of availability of testing facility for drug product along with analytical procedure.	
347.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Capsule Section (General)
	Brand Name + Dosage Form and Strength	FERIX 150 mg Capsule.
	Composition	Each Capsule Contains; Iron polysaccharide Complex equivalent to Elemental Iron …… 150 mg
	Dairy No. date of R &I fee	Dy. No. 14839, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760171
	Pharmacological Group	Antianemic preparations, Iron trivalent, oral preparations ATC Code: B03AB02
	Type of form	Form-5
	Finished product specifications	ARP Specifications.
	Pack size and Demand Price	3x10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	NA

	Me-too-status	Ferricure Capsule Reg. No. 050637 M/s SJ & G Fazul Ellahie, , Karachi
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities. Registration letter shall be issued after submission of fee Rs. 7500/- for revision of specifications.	
348.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Semi Solids Cream/ointment/Gel Section (General)
	Brand Name + Dosage Form and Strength	FUNOKET CREAM 2%
	Composition	Each gram of Cream contains; Ketoconazole …….. 2% W/W (20 mg)
	Dairy No. date of R &I fee	Dy. No. 14838, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760170
	Pharmacological Group	Imidazole and triazole derivatives ATC Code: D01AC08
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	1 x 5g, 10g, 15g. As per SRO
	Approval status of product in Reference Regulatory Authorities	Daktarin Gold 2% Cream M/s McNeil Products Limited MHRA Approved
	Me-too-status	Ramaket Cream 2% w/w Reg. No. 096908 M/s Caliph Pharmaceuticals (Pvt) Ltd., Plot No. 17 Industrial Estate Risalpur
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved.	
349.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Sachet Section (General)
	Brand Name + Dosage Form and Strength	MUCAID 200 mg Powder for Oral Solution
	Composition	Each Sachet Contains; Acetylcysteine powder for oral solution …… 200 mg
	Dairy No. date of R &I fee	Dy. No. 14841, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760173
	Pharmacological Group	Expectorants, Excl. Combinations With Cough Suppressants, Mucolytics. ATC Code: R05CB01
	Type of form	Form-5
	Finished product specifications	ARP Specifications.
	Pack size and Demand Price	30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Acetylcysteine 200 mg Powder for Oral Solution (Sachet) M/s Sovereign Medical UK MHRA Approved.
	Me-too-status	Acekan 200mg Sachets Reg. No. 077289 M/s Jaskan Pharmaceuticals (Pvt) Ltd. , Plot No. 50 Sunder Industrial Estate Lahore
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved with innovator's Specifications. Registration letter shall be issued after	

	submission of fee Rs. 7500/- for revision of specifications.	
350.	Name and address of manufacture / Applicant	M/s ARP (Pvt) Ltd., Plot No. 12 & 12 A, Street No. W-3, National Industrial Zone Rawat. (DML No. 000682) Semi Solids Cream/ointment/Gel Section (General)
	Brand Name + Dosage Form and Strength	BIFOTEN 1% Cream
	Composition	Each gram of Cream Contains; Bifonazole …… 1%(W/W) (10mg)
	Dairy No. date of R &I fee	Dy. No. 14848, dated 07.03.2019. Fee Paid: Rs. 20,000/- dated 06.03.2019 vide slip No. 0760180
	Pharmacological Group	Antifungal for Topical Use ATC Code: D01AC10
	Type of form	Form-5
	Finished product specifications	ARP Specifications.
	Pack size and Demand Price	15g tube. As per SRO
	Approval status of product in Reference Regulatory Authorities	Canesten Bifonazole Cream The cream contains 1% w/w bifonazole M/s Bayer plc Consumer Care Division England MHRA Approved.
	Me-too-status	Canesten Extra Cream Reg. No. 007484 M/s Bayer Pakistan (Pvt) Ltd., C-21, S.I.T.E, Karachi
	GMP Status	Last inspection conducted on 28.12.2021. The GMP status is reported as compliant.
	Remark of the Evaluator.	
	Decision: Approved with innovator's Specifications. Registration letter shall be issued after submission of fee Rs. 7500/- for revision of specifications.	
351.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Capsule Section (General Antibiotic)
	Brand Name + Dosage Form and Strength	DEXAZOL Capsule 60 mg
	Composition	Each Dual Delayed Release Capsule Contains; Dexlansoprazole……...60 mg
	Dairy No. date of R &I fee	Dy. No. 16573 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822188 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC06
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	14's 28's, as per SRO
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed-release capsules, for oral use Delayed-release capsules: 30 mg and 60 mg MHRA Approved.
	Me-too-status	Remit DR Capsules 30 mg Reg. No. 090301 M/s Scotmann Pharmaceuticals Plot No. 5-D, Sector I-10/3 Islamabad.
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	1. Source of pellets: M/s Vision Pharma
	Decision: Deferred for stability study data as per guidelines provided in 293rd meeting of Registration Board.	
352.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Capsule Section (General Antibiotic)

	Brand Name + Dosage Form and Strength	DEXAZOL Capsule 30 mg
	Composition	Each Dual Delayed Release Capsule Contains; Dexlansoprazole……....30 mg
	Dairy No. date of R &I fee	Dy. No. 16572 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822187 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC06
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	14's 28's, as per SRO
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed-release capsules, for oral use Delayed-release capsules: 30 mg and 60 mg MHRA Approved.
	Me-too-status	Daplazole DDR Capsule 30 mg Reg. No. 104251 M/s AGP Ltd. Karachi.
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	1. Source of pellets M/s Vision Pharma
	Decision: Deferred for stability study data as per guidelines provided in 293rd meeting of Registration Board.	
353.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Tablet Section (General)
	Brand Name + Dosage Form and Strength	Levosol Tablets 25 mg
	Composition	Each Tablet Contains; Levosulpiride ……. 25 mg
	Dairy No. date of R &I fee	Dy. No. 16577 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822192 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIPSYCHOTICS, Benzamides, ATC Code:N05AL07
	Type of form	Form-5
	Finished product specifications	Manufacturers Specifications.
	Pack size and Demand Price	10's,14's, 20's, 30's, A+s per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved.
	Me-too-status	Sulvoric 25mg Tablet Reg. No.070484 M/s High-Q
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	
	Decision: Approved.	
354.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Tablet Section (General)
	Brand Name + Dosage Form and Strength	TERBINA TABLET 125 mg
	Composition	Each Tablet Contains; Terbinafine HCl equivalent to Terbinafine…. 125 mg
	Dairy No. date of R &I fee	Dy. No. 16575 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822190 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antifungals for systemic use.

		ATC Code: D01BA02
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	TERBINAFINE 125MG TABLETS (TERBINAFINE HYDROCHLORIDE) MHRA Approved
	Me-too-status	Brandit Tablet 125 mg Reg. No. 090822 M/s High-Q Pharmaceuticals Karachi.
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	1. The Label claim of RRA approved products is for Terbinafine base 125 mg as HCl Salt, the applied label claim needs to be revised accordingly along with submission of requisite fee(Full fee). **The firm has revised the label claim as per RRA approved product along with submission of Fee Rs. 7500/- vide Slip No. 2743183351 dated 04.10.2022**
	Decision: Approved. Registration letter shall be issued after submission of differential fee of Rs. 22,500/- by the firm for pre-approval change for equivalency as per as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
355.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Tablet Section (General)
	Brand Name + Dosage Form and Strength	TERBINA TABLET 250 mg
	Composition	Each Tablet Contains; Terbinafine HCl equivalent to Terbinafine…. 250 mg
	Dairy No. date of R &I fee	Dy. No. 16574 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822189 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antifungals for systemic use. ATC Code: D01BA02
	Type of form	Form-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	10's. As per SRO
	Approval status of product in Reference Regulatory Authorities	TERBINAFINE 250MG TABLETS (TERBINAFINE HYDROCHLORIDE) MHRA Approved
	Me-too-status	Brandit Tablet 250 mg Reg. No. 090823 M/s High-Q Pharmaceuticals Karachi.
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	1. The Label claim of RRA approved products is for Terbinafine base 250 mg as HCl Salt, the applied label claim needs to be revised accordingly along with submission of requisite fee(Full Fee). **The firm has revised the label claim as per RRA approved product along with submission of Fee Rs. 7500/- vide Slip No. 387779024 dated 04.10.2022**
	Decision: Approved. Registration letter shall be issued after submission of differential fee of Rs. 22,500/- by the firm for pre-approval change for equivalency as per as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
356.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No.

		000514) Cream/ ointment/ Gel (General)
	Brand Name + Dosage Form and Strength	ARSIBACT-H CREAM 15gm
	Composition	Each gram of cream contains; Fusidic acid….. 20 mg Hydrocortisone acetate…… 10 mg
	Dairy No. date of R &I fee	Dy. No. 16569 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822184 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Corticosteroids, weak, combinations with antibiotics ATC Code: D07CA01
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	15gm. Rs. 250/- per tube.
	Approval status of product in Reference Regulatory Authorities	FUCIDIN® H Fusidic acid and Hydrocortisone acetate 2% / 1% Cream Health Canada Approved.
	Me-too-status	Fusiwin-H Cream Reg. No. 062471 M/s Hoover Pharmaceuticals Lahore.
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	
	Decision: Approved.	
357.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Cream/ Ointment/ Gel (General)
	Brand Name + Dosage Form and Strength	TERBINA 10MG CREAM
	Composition	Each gram of cream contains; Terbinafine HCl…10mg
	Dairy No. date of R &I fee	Dy. No. 16576 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822191 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Other antifungals for topical use. ATC Code: D01AE15
	Type of form	Form-5
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	10gm, as per SRO
	Approval status of product in Reference Regulatory Authorities	LAMISIL 1% w/w Cream MHRA Approved.
	Me-too-status	Lamisil Cream 1 % M/s GSK Petaro Road Jamshoro.
	GMP Status	Inspection report provided is dated 02.01.2018. Latest inspection report is required.s
	Remark of the Evaluator.	
	Decision: Approved.	
358.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Cream/Ointment/Gel (General)
	Brand Name + Dosage Form and Strength	ARSONE OINTMENT 15GM
	Composition	Each Tube Contains; Mometasone Furoate …….1mg/g

	Dairy No. date of R &I fee	Dy. No. 16570 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822185 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	CORTICOSTEROIDS, PLAIN, Corticosteroids, potent (group III) ATC Code: D07AC13
	Type of form	Form-5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	1's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Mometasone Furoate 0.1% W/W Oitnment. MHRA Approved
	Me-too-status	Biometa Ointment Reg. No. 08619 M/s Bio-Labs Islamabad
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	
	Decision: Approved. Firm shall submit evidence of availability of separate dispensing booth for steroidal formulations, before issuance of registration letter.	
359.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Cream/ Oitnment/ Gel (General)
	Brand Name + Dosage Form and Strength	CLINDACIN GEL 30GM
	Composition	Each Gram Contains; Clindamycin Phosphate equivalent to Clindamycin 1% w/w
	Dairy No. date of R &I fee	Dy. No. 16571 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822186 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antiinfectives for treatment of acne ATC Code: D10AF01
	Type of form	Form-5
	Finished product specifications	USP Specifications.
	Pack size and Demand Price	30 gm, Rs. 320/- per Tube
	Approval status of product in Reference Regulatory Authorities	ZINDACLIN clindamycin (as clindamycin phosphate) 1% topical gel tube TGA Australia Approved.
	Me-too-status	Daymac gel 10mg Reg. No. 062452 M/s Hoover Pharmaceuticals Lahore.
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	
	Decision: Approved.	
360.	Name and address of manufacture / Applicant	M/s Arsons Pharmaceutical (Pvt.) Ltd. 2.5 Km Defence Road, off Multan Road Lahore Pakistan. (DML No. 000514) Cream/ Ointment/ Gel (General)
	Brand Name + Dosage Form and Strength	ARSIBACT-B CREAM 15GM
	Composition	Each Gram Cream Contains; Fusidic Acid……. 20mg Betamethasone as Valerate ….. 1mg
	Dairy No. date of R &I fee	Dy. No. 16568 dated 07.03.2019. Fee Rs. 20,000/- paid vide voucher No. 0822183 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics, betamethasone and antibiotics. ATC Code: D07CC01

	Type of form	Form-5
	Finished product specifications	Innovator's Specifications.
	Pack size and Demand Price	15gm, Rs. 350/- per tube.
	Approval status of product in Reference Regulatory Authorities	Fusidic acid/Betamethasone 20 mg/g + 1mg/g cream MHRA Approved.
	Me-too-status	Fuswin-B Cream Reg. No. 062470 M/s Hoover Pharmaceuticals Lahore.
	GMP Status	Inspection report provided is dated 29.09.2021. GMP status is good.
	Remark of the Evaluator.	1. Specifications of Finished products are not provided. 2. The label claim is required to be revised, the reference RRA approved product mentions 1mg Betamethasone as valerate. Also submit requisite fee (Full Fee). **The firm was communicated the observations. The firm has mentioned that finished product specifications will be innovator's specifications and has revised the label claim from "betamethasone valerate" to "betamethasone as valerate". Along with submission of Fee Rs. 7500/- vide slip No. 2935179779 dated 04.10.2022. The firm has not submitted full fee.**
	Decision: Approved. Registration letter shall be issued after submission of differential fee of Rs. 22,500/- by the firm for pre-approval change for equivalency as per as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
361.	Name and address of manufacture / Applicant	M/s Avensis Pharmaceuticals, (DML No. 000894) Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi. Tablet (Psychotropic) Section
	Brand Name + Dosage Form and Strength	Dormilam Tablet 7.5mg
	Composition	Each Tablet contains; Midazolam …..7.5 mg (as midazolam maleate)
	Dairy No. date of R &I fee	Dy. No. 17394 dated 07.03.2019. Fee paid Rs. 20,000/- vide Deposit Slip No. 0761618 dated 05.03.2019. Endorsed on 07.03.2019.
	Pharmacological Group	Benzodiazepine derivatives. ATC Code: N05CD08
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dormicum 7.5 mg film-coated tablets Bfarm Germany Approved.
	Me-too-status	Dormicum Tablet 7.5mg Reg. No. 011231 M/s Martin Dow Marker Quetta.
	GMP Status	Last inspection conducted on 31.08.2021. Status is OK.
	Remark of the Evaluator.	The reference product is film coated, whereas applied product is not film coated. Clarification/ correction is required along with submission of requisite fee.
	Decision: Approved as film coated tablet and change of brand name. Registration letter shall be issued after submission of revised formulation of film coated tablet and Rs. 7500/- fee for pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
362.	Name and address of manufacture / Applicant	M/s Avensis Pharmaceuticals,(DML No. 000894) Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi. Tablet (Psychotropic) Section
	Brand Name + Dosage Form and Strength	MS Contin Tablet 10 mg

	Composition	Each Tablet contains; Morphine Sulphate…….. 10 mg
	Dairy No. date of R &I fee	Dy. No. 17376 dated 07.03.2019. Fee paid Rs. 20,000/- vide Deposit Slip No. 0841045 dated 05.03.2019. Endorsed on 07.03.2019.
	Pharmacological Group	Analgesics, Natural opium alkaloids ATC Code: N02AA01
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too-status	Qonza 10mg Tablet Reg. No. 071221 M/s Wilshire Laboratories Lahore.
	GMP Status	Last inspection conducted on 31.08.2021. Status is OK.
	Remark of the Evaluator.	1. The Pharmacological group is mentioned as Anti pyretic. It needs to be corrected along with submission of requisite fee. 2. The evidence of approval in RRA is required. Provided reference was not of registered product in RRA. 3. Form-5 and undertaking submitted are unsigned. Signed Undertakings and Form-5 are required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
363.	Name and address of manufacture / Applicant	M/s Avensis Pharmaceuticals,(DML No. 000894) Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi. Tablet (Psychotropic) Section
	Brand Name + Dosage Form and Strength	Soseget 25mg Tablet
	Composition	Each tablet Contains; Pentazocine HCl…… 25 mg
	Dairy No. date of R &I fee	Dy. No. 17402 dated 07.03.2019. Fee paid Rs. 20,000/- vide Deposit Slip No. 0841048 dated 05.03.2019. Endorsed on 07.03.2019.
	Pharmacological Group	Opioid analgesics, Benzomorphan derivatives ATC Code: N02AD01
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	PENTAZOCINE TABLETS BP 25mg MHRA Approved.
	Me-too-status	Segon Tablet Reg. No. 060093 M/s Aries Pharmaceuticals Peshawar.
	GMP Status	Last inspection conducted on 31.08.2021. Status is OK.
	Remark of the Evaluator.	The Pharmacological group is mentioned as psychotropic. It needs to be corrected along with submission of requisite fee.
	Decision: Approved and change of brand name. Registration letter shall be issued after submission of correct pharmacological group along with fee Rs. 7500/- for pre-approval changes as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
364.	Name and address of manufacture / Applicant	M/s Avensis Pharmaceuticals,(DML No. 000894) Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi. Tablet (Psychotropic) Section

	Brand Name + Dosage Form and Strength	Rita 10 mg Tablet
	Composition	Each Tablet Contains; Methylphanidate HCl……..10 mg
	Dairy No. date of R &I fee	Dy. No. 17401 dated 07.03.2019. Fee paid Rs. 20,000/- vide Deposit Slip No. 0841049 dated 05.03.2019. Endorsed on 07.03.2019.
	Pharmacological Group	PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, Centrally acting sympathomimetics. ATC code: N06BA04
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ritalin® 10mg Tablets MHRA Approved.
	Me-too-status	Ritalin 10 mg Tablet Reg. No. 004458 M/s Novartis Pharma Karachi.
	GMP Status	Last inspection conducted on 31.08.2021. Status is OK.
	Remark of the Evaluator.	
	Decision: Approved and change of brand name.	
365.	Name and address of manufacture / Applicant	M/s Avensis Pharmaceuticals,(DML No. 000894) Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi. Tablet (Psychotropic) Section
	Brand Name + Dosage Form and Strength	TimeGesic Sublingual Tablet 0.2 mg
	Composition	Each sublingual tablet contains; Buprenorphine HCl eq. to Buprenoprhine Base 0.2mg
	Dairy No. date of R &I fee	Dy. No. 17400 dated 07.03.2019. Fee paid Rs. 20,000/- vide Deposit Slip No. 0841050 dated 05.03.2019. Endorsed on 07.03.2019.
	Pharmacological Group	Opioid analgesics, Oripavine derivatives. ATC Code: N02AE01
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	TEMGESIC buprenorphine 200 microgram (as hydrochloride) sublingual tablet bottle. TGA Australia Approved.
	Me-too-status	Enorfine Sublingual Tablets Reg. No. 041527 M/s Munawar Pharma (Pvt) Ltd., 31-Km Multan Road Lahore.
	GMP Status	Last inspection conducted on 31.08.2021. Status is OK.
	Remark of the Evaluator.	
	Decision: Approved and change of brand name.	
366.	Name and address of manufacture / Applicant	M/s Avensis Pharmaceuticals, (DML No. 000894) Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi. Dry Powder Suspension (Cephalosporin) Section
	Brand Name + Dosage Form and Strength	VIOCEF DS Dry Suspension 250mg/5ml
	Composition	Each 5 ml after reconstitution contains; Cefradine B.P .250 mg
	Dairy No. date of R &I fee	Dy. No. 17413 dated 07.03.2019. Fee paid Rs. 20,000/- vide Deposit Slip No. 0839023 dated 05.03.2019. Endorsed on 07.03.2019.
	Pharmacological Group	First-generation cephalosporins

		ATC Code: J01DB09
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nicef Syrup 250mg/5ml / Cefradine Syrup 250mg/5ml MHRA Approved.
	Me-too-status	Cefrinex Suspension 250mg/5ml Reg. No. 015126 M/s Bosch Pharmaceuticals Karachi.
	GMP Status	Last inspection conducted on 31.08.2021. Status is OK.
	Remark of the Evaluator.	The applied product is dry powder for suspension. In reference RRA approved product, after reconstitution syrup is formed.
	Decision: Approved.	
367.	Name and address of manufacture / Applicant	M/s Avensis Pharmaceuticals, (DML No. 000894) Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi. SVP Infusion (General) Section
	Brand Name + Dosage Form and Strength	Moxiflox 400mg/250ml
	Composition	Each 250 ml Infusion contains; Moxifloxacin …400mg as moxifloxacin HCl.
	Dairy No. date of R &I fee	Dy. No. 17381 dated 07.03.2019. Fee paid Rs. 20,000/- vide Deposit Slip No. 0841044 dated 05.03.2019. Endorsed on 07.03.2019.
	Pharmacological Group	Fluoroquinolones. ATC Code: J01MA14
	Type of form	Form-5
	Finished product specifications	BP Specifications.
	Pack size and Demand Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Avelox 400 mg/250 ml solution for infusion MHRA Approved.
	Me-too-status	Avelox Infusion Reg. No. 030851 M/s Bayer Pakistan (Pvt.) Ltd. Kot Lakhpat.
	GMP Status	Last inspection conducted on 31.08.2021. Status is OK.
	Remark of the Evaluator.	Chemical name of product is written as Morphine 10 mg.
	Decision: Approved.	
368	Name and address of manufacturer/ Applicant	M/s Trigon Pharmaceuticals (Pvt) Ltd. Raiwind Road, Block B LDA Avenue Phase-I, Lahore. (Contract Giver) (DML No. 000342). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	ESOMERPRAGON 40mg Injection. (IV)
	Composition	Each Vial Contains; Esomeprazole (as sodium)…… 40mg
	Diary No. Date of R & I & fee	Dy.No.16133 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1900491 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION - PL 55035/0001 MHRA APPROVED.
	Me-too status	Nexum IV 40mg Injection. Reg. No. 050651 M/s Getz Pharma Karachi.
	GMP status	Last GMP inspection of m/s English pharma, conducted on 15-07-2022 concludes satisfactory compliance.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Trigon Pharmaceuticals is required. iii. Section approval letter of M/s English Pharmaceuticals is required. iv. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; o Dry Powder Injectable (Penicillin) o Liquid ampoule Injectable (General) o Dry powder Lyophilized Injectable (General) o Large Volume Vial Injectable (General)
	Decision: Approved. Registration letter shall be issued after submission of correct address of applicant along with fee of Rs. 75,000/-. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**	
369	Name and address of manufacturer/ Applicant	M/s Trigon Pharmaceuticals (Pvt) Ltd. Raiwind Road, Block B LDA Avenue Phase-I, Lahore. (Contract Giver) (DML No. 000342). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	OMERPRAGON 40mg Injection. (IV)
	Composition	Each Vial Contains; Omeprazole (as sodium)…… 40mg
	Diary No. Date of R & I & fee	Dy.No.16134 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1900490 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC01
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion (omeprazole sodium) - PL 10622/0232 MHRA APPROVED.
	Me-too status	Risek 40mg Infusion Reg. No. 024170 M/s Getz Pharma Karachi.
	GMP status	Last GMP inspection of m/s English pharma, conducted on 15-07-2022 concludes satisfactory compliance.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required.

		ii. Copy of DML of M/s Trigon Pharmaceuticals is required. iii. Section approval letter of M/s English Pharmaceuticals is required.
	Decision: Approved. The registration letter shall be issued after submission of correct address of applicant along with fee of Rs. 75,000/-. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**	
370	Name and address of manufacturer/ Applicant	M/s Alen Pharmaceuticals, Plot No. 138-A, Nowshera Industrial Estate Mardan Road, Risalpur. (Contract Giver) (DML No. 000435). & M/s Bio-Labs (Pvt) Ltd, Plot No. 145 Industrial Triangle, Kahuta Road, Islamabad (Contract acceptor) (DML No. 000296)
	Brand Name + Dosage Form + Strength	Allazole 100mg/50ml I.V Infusion
	Composition	Each 50ml contains: Fluconazole……100mg
	Diary No. Date of R & I & fee	Dy.No.16810 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0815832 dated 27.02.2019, endorsed on 06.03.2019
	Pharmacological Group	ANTIMYCOTICS FOR SYSTEMIC USE, Triazole and tetrazole derivatives. ATC Code: J02AC01
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Fluconazole 2mg/ml solution for infusion. 50ml, 100ml, 200ml. MHRA Approved
	Me-too status	Could not be verified.
	GMP status	Last GMP inspection was conducted on 05-12-2017 and 06-12-2017. GMP audit performa stated that Liquid Infusion 100ml (General) Section was found GMP compliant. However, GMP certificate was not attached.
	Remarks of the Evaluator	i.Copy of latest GMP inspection report/ certificate of M/s Bio-Labs is required is required. ii. Copy of DML of M/s Alen Pharmaceuticals is required. iii. Copy of section approval letter of M/s Bio-Labs is required. iv. Me too reference could not be verified. Proper me too reference is required.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	
371	Name and address of manufacturer/ Applicant	M/s Ambrosia Pharmaceuticals, Plot no. 18, Street No. 09, National Industrial Zone, Rawat. (DML No. 000561) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Ambstin 10mg Tablet
	Composition	Each Film Coated tablet Ebastine…….10mg

	Diary No. Date of R & I & fee	Dy. No. 16028 dated 07-03-2019. Fee paid Rs. 20,000/- vide slip No. 1900244 dated 07.03.2019 endorsed on 07.03.2019.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX22
	Type of Form	Form-5
	Finished product Specification	JP Specifications.
	Pack size & Demanded Price	10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Ebastine Viatris 10mg film-coated tablet ANSM, France Approved.
	Me-too status	Mestin 10mg Tablet Reg. No. 094054 M/s Metro Pharmaceuticals Rawat.
	GMP status	Last Panel inspection conducted on 28.12.2021. GMP status is Good.
	Remarks of the Evaluator	
	Decision: Approved.	
372	Name and address of manufacturer/ Applicant	M/s Ambrosia Pharmaceuticals, Plot no. 18, Street No. 09, National Industrial Zone, Rawat. (DML No. 000561) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Ambstin 20mg tablet.
	Composition	Each Film Coated tablet Ebastine…….20mg
	Diary No. Date of R & I & fee	Dy. No. 16029 dated 07-03-2019. Fee Paid Rs. 20,000/- vide Slip No. 1900245 dated 07.03.2019.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX22
	Type of Form	Form-5
	Finished product Specification	JP Specifications.
	Pack size & Demanded Price	10's, as per SRO
	Approval status of product in Reference Regulatory Authorities	ALASTINA 20mg CIMA, Spain Approved.
	Me-too status	Kestine 20 mg tablet Reg. No. 025432 M/s Highnoon Laboratories Ltd Lahore.
	GMP status	Last Panel inspection conducted on 28.12.2021. GMP status is Good.
	Remarks of the Evaluator	
	Decision: Approved.	
373	Name and address of manufacturer/ Applicant	M/s Alfalah Pharma (pvt), Ltd, 12-Km, Sheikhupura Road, Lahore (contract giver) (DML No. 000461) M/s Synchro Pharmaceuticals, 77-Industrial Estate, Kot Lakhpat, Lahore (Contract Acceptor) (DML No. 000575) Dry Powder Suspension (Cephalosporin)
	Brand Name + Dosage Form + Strength	Vasix Dry Suspension 200mg/5ml
	Composition	Each 5 ml Contains; Cefixime Trihydrate equivalent to Cefixime 200mg
	Diary No. Date of R & I & fee	Dy. No. 16421 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0795641 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD08
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	USP Specification

	Pack size & Demanded Price	01×30ml as per SRO
	Approval status of product in Reference Regulatory Authorities	Suprax 200mg/5ml FDA Approved.
	Me-too status	Cefspan D.S Suspension Reg. No. 024634 M/s Barret Hodgson Pakistan Karachi.
	GMP status	Last inspection conducted on 22.01.21
	Remarks of the Evaluator	
	Decision: Approved.	
374	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad. (Contract acceptor) (DML No. 000517) Injection (General) Section.
	Brand Name + Dosage Form + Strength	CHEMSET 8mg/4ml Injection (IV/IM)
	Composition	Each 4ml Ampoule Contains; Ondansetron hydrochloride dehydrate eq. to Ondansetron ……8mg
	Diary No. Date of R & I & fee	Dy.No.16455 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844419 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists ATC Code: A04AA01
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	4ml x 5's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ONDANSETRON 8MG/4ML INJECTION (ONDANSETRON HYDROCHLORIDE) PL 04543/0508 MHRA APPROVED.
	Me-too status	Periset 4ml injection Reg. No. 090250 M/s Linear Pharma Islamabad.
	GMP status	Last inspection conducted on 28.10.2020. GMP Status is good.
	Remarks of the Evaluator	i. Copy of DML of M/s Fresh Pharma is required. ii. Copy of Section Approval letter of M/s Vision Pharma is required. iii. Form-5 filled and signed by M/s Fresh Pharma is required. iv. Capacity assessment inspection of M/s Vision Pharmaceutical (DML No. 000517) was conducted on 15.06.2022 for following sections; a. Sterile Dry Powder Vial (General) b. Sterile Dry Powder Injection Vial (Steroid)
	Decision: Deferred for submission of Form-5 by M/s Fresh Pharmaceuticals along with fee of Rs. 75,000/- as per notification No. 7-11/2012-B&A/DRAP dated 07.05.2021.	
375	Name and address of manufacturer/ Applicant	M/s Inventor Pharma, Plot No. K-196, SITE (SHW) PH-II, Karachi. (Contract Giver) (DML No. 000866). Contract with

		M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad. (Contract acceptor) (DML No. 000517) Dry Powder Injection (Steroid) Section.
	Brand Name + Dosage Form + Strength	NEOCARTIF 100mg Inejction (IV)
	Composition	Each Vial Contains; Hydrocortisone Sodium Succinate equivalent to Hydrocortisone……100mg
	Diary No. Date of R & I & fee	Dy.No.16407 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844286 dated 4.03.2019, endorsed on 06.03.2019
	Pharmacological Group	CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, Glucocorticoids. ATC Code: H02AB09
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO
	Approval status of product in Reference Regulatory Authorities	SOLU-CORTEF 100MG, HYDROCORTISONE 100 MG POWDER FOR SOLUTION FOR INJECTION OR INFUSION. MHRA APPROVED.
	Me-too status	Hyzonate Injection 100mg Reg. No. 019228 M/s Amson Vaccines & Pharma (Pvt.) Ltd. Islamabad.
	GMP status	Last inspection conducted on 28.10.2020. GMP Status is good.
	Remarks of the Evaluator	i. Capacity assessment inspection of M/s Vision Pharmaceutical (DML No. 000517) was conducted on 15.06.2022 for following sections; a. Sterile Dry Powder Vial (General) b. Sterile Dry Powder Injection Vial (Steroid)
	Decision: Approved with change of brand name.	
376	Name and address of manufacturer/ Applicant	M/s Inventor Pharma, Plot No. K-196, SITE (SHW) PH-II, Karachi. (Contract Giver) (DML No. 000866). Contract with M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad. (Contract acceptor) (DML No. 000517) Sterile Dry Powder Injectable vial (General) Section.
	Brand Name + Dosage Form + Strength	PROMEP 40mg IV Injection
	Composition	Each Vial Contains; Esomeprazole as Sodium…….40mg
	Diary No. Date of R & I & fee	Dy.No.16409 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0825726 dated 4.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors, ATC Code: A02BC05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Innovator's Specifications.
	Pack size & Demanded Price	1's As per SRO.
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION - PL 55035/0001 MHRA APPROVED.
	Me-too status	Nexum IV 40mg Injection Reg. No. 050651 M/s Getz Pharma Karachi.

	GMP status	Last inspection conducted on 28.10.2020. GMP Status is good.
	Remarks of the Evaluator	i. Capacity assessment inspection of M/s Vision Pharmaceutical (DML No. 000517) was conducted on 15.06.2022 for following sections; a. Sterile Dry Powder Vial (General) b. Sterile Dry Powder Injection Vial (Steroid)
	Decision: Approved.	
377	Name and address of manufacturer/ Applicant	M/s Inventor Pharma, Plot No. K-196, SITE (SHW) PH-II, Karachi. (Contract Giver) (DML No. 000866). Contract with M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad. (Contract acceptor) (DML No. 000517) Sterile Dry Powder Injectable vial (General) Section.
	Brand Name + Dosage Form + Strength	OMETEK 40mg IV Injection
	Composition	Each Vial Contains; Omeprazole as Sodium ……. 40mg
	Diary No. Date of R & I & fee	Dy.No.16408 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844287 dated 4.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors, ATC Code: A02BC01
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Innovator's Speceifications.
	Pack size & Demanded Price	1's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Powder for Solution for Infusion (omeprazole sodium) - PL 10622/0232 MHRA Approved.
	Me-too status	Risek 40mg Infusion Reg. No. 024170 M/s Getz Pharma Karachi.
	GMP status	Last inspection conducted on 28.10.2020. GMP Status is good.
	Remarks of the Evaluator	i. Capacity assessment inspection of M/s Vision Pharmaceutical (DML No. 000517) was conducted on 15.06.2022 for following sections; a. Sterile Dry Powder Vial (General) b. Sterile Dry Powder Injection Vial (Steroid)
	Decision: Approved.	
378	Name and address of manufacturer/ Applicant	M/s Winilton Pharmaceuticals (Pvt.) Ltd. Plot No. 45 St. No. S-5, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000721). Contract with M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad. (Contract acceptor) (DML No. 000517) Injection (General) Section.
	Brand Name + Dosage Form + Strength	WINDSTON 8mg/4ml Injection (IV/IM)
	Composition	Each 4ml Ampoule Contains; Ondansetron hydrochloride dehydrate eq. to Ondansetron ……8mg

	Diary No. Date of R & I & fee	Dy.No.16399 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0807475 dated 06.03.2019, endorsed on 06.03.2019
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists ATC Code: A04AA01
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	4ml x 5's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ONDANSETRON 8MG/4ML INJECTION (ONDANSETRON HYDROCHLORIDE) PL 04543/0508 MHRA APPROVED.
	Me-too status	Periset 4ml injection Reg. No. 090250 M/s Linear Pharma Islamabad.
	GMP status	Last inspection conducted on 28.10.2020. GMP Status is good.
	Remarks of the Evaluator	ii. Copy of DML of M/s Winilton Pharma is required. iii. Copy of Section Approval letter of M/s Vision Pharma is required. iv. Capacity assessment inspection of M/s Vision Pharmaceutical (DML No. 000517) was conducted on 15.06.2022 for following sections; a. Sterile Dry Powder Vial (General) b. Sterile Dry Powder Injection Vial (Steroid)
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals.	
379	Name and address of manufacturer/ Applicant	M/s Winilton Pharmaceuticals (Pvt.) Ltd. Plot No. 45 St. No. S-5, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000721). Contract with M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad. (Contract acceptor) (DML No. 000517) Injection (General) Section.
	Brand Name + Dosage Form + Strength	WINMOX 400mg/250ml IV Infusion.
	Composition	Each 250ml Contains; Moxifloxacin Hydrochloride equivalent to Moxifloxacin ……. 400mg
	Diary No. Date of R & I & fee	Dy.No.16398 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0807474 dated 06.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14.
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Manufacturer's Specifications.
	Pack size & Demanded Price	1x250ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MOXIFLOXACIN 400 MG/250 ML SOLUTION FOR INFUSION - PL 24598/0022; UK/H/4829/001/DC. MHRA APPROVED.
	Me-too status	Avelox Infusion Reg. No. 109733 M/s Bayer Pakistan Kot Lakhpat.
	GMP status	Last inspection conducted on 28.10.2020. GMP Status is good.

	Remarks of the Evaluator	v.Capacity assessment inspection of M/s Vision Pharmaceutical (DML No. 000517) was conducted on 15.06.2022 for following sections; c. Sterile Dry Powder Vial (General) d. Sterile Dry Powder Injection Vial (Steroid)
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals.	
380	Name and address of manufacturer/ Applicant	M/s Nimrall Laboratories, Plot No. 24, St. No. SS-3, National Industrial Zone, Rawat. (Contract Giver) (DML No. 000611). Contract with M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road Islamabad. (Contract acceptor) (DML No. 000517) Injection (General) Section.
	Brand Name + Dosage Form + Strength	METHRALL 1M IU Injection (IV)
	Composition	Each Vial Contains; Colistimethate Sodium dry powder ….1Million I.U
	Diary No. Date of R & I & fee	Dy.No.13921 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0713447 dated 06.03.2019, endorsed on 06.03.2019
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists ATC Code: A04AA01
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	COLISTIMETHATE SODIUM 1 MIU POWDER FOR SOLUTION FOR INJECTION/INFUSION - PL 24598/0091 MHRA Approved.
	Me-too status	Stacolmi 1MIU Injection Reg. No. 106475 M/s Stallion Pharmaceuticals Lahore.
	GMP status	Last inspection conducted on 28.10.2020. GMP Status is good.
	Remarks of the Evaluator	i. Copy of DML of M/s Nimrall Pharma is required. ii.Copy of Section Approval letter of M/s Vision Pharma is required. iii.Capacity assessment inspection of M/s Vision Pharmaceutical (DML No. 000517) was conducted on 15.06.2022 for following sections; a. Sterile Dry Powder Vial (General) b. Sterile Dry Powder Injection Vial (Steroid)
	Decision: Approved. Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
381	Name and address of manufacturer/ Applicant	M/s Kohinoor Industries 160/B, Small Industries Estate Sahiwal. (Contract Giver) (DML No. 000197). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)

		Dry Powder for Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	KOXONE 250mg Injection (IM)
	Composition	Each Vial Contains; Ceftriaxone as Sodium ……..250mg
	Diary No. Date of R & I & fee	Dy.No.16876 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0834716 dated 7.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg Powder for Solution for Injection - PL 24598/0006. MHRA Approved.
	Me-too status	Rocephin IM Inj Reg. No. 008432 M/s Martin Dow Ltd. Karachi.
	GMP status	Last GMP inspection was conducted on 16.01.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Kohinoor Industries is required. iii. Section approval letter of M/s English Pharmaceuticals is required. iv. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; a. Dry Powder Injectable (Penicillin) b. Liquid ampoule Injectable (General) c. Dry powder Lyophilized Injectable (General) d. Large Volume Vial Injectable (General)
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.	
382	Name and address of manufacturer/ Applicant	M/s Kohinoor Industries 160/B, Small Industries Estate Sahiwal. (Contract Giver) (DML No. 000197). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	KOXONE 500mg Injection (IM)
	Composition	Each Vial Contains; Ceftriaxone as Sodium ……..500mg
	Diary No. Date of R & I & fee	Dy.No.16877 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0834717 dated 7.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Rocephin IM Inj Reg. No. 008434 M/s Martin Dow Ltd. Karachi.
	GMP status	Last GMP inspection was conducted on 16.01.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Kohinoor Industries is required. iii. Section approval letter of M/s English Pharmaceuticals is required. iv. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; o Dry Powder Injectable (Penicillin) o Liquid ampoule Injectable (General) o Dry powder Lyophilized Injectable (General) o Large Volume Vial Injectable (General)
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.	
383	Name and address of manufacturer/ Applicant	M/s Kohinoor Industries 160/B, Small Industries Estate Sahiwal. (Contract Giver) (DML No. 000197). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	KOXONE 1g Injection. (IV)
	Composition	Each Vial Contains; Ceftriaxone as Sodium……1gm
	Diary No. Date of R & I & fee	Dy.No.16878 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0834718 dated 7.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 1g Powder for Solution for Injection or Infusion (ceftriaxone sodium) - PL 42671/0001 MHRA Approved.
	Me-too status	Rocephin IV Inj. Reg. No. 008437 M/s Roche Pakistan Ltd. Karachi.
	GMP status	Last GMP inspection was conducted on 16.01.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Kohinoor Industries is required.

		iii. Section approval letter of M/s English Pharmaceuticals is required. iv. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; o Dry Powder Injectable (Penicillin) o Liquid ampoule Injectable (General) o Dry powder Lyophilized Injectable (General) o Large Volume Vial Injectable (General)
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.	
384	Name and address of manufacturer/ Applicant	M/s Kohinoor Industries 160/B, Small Industries Estate Sahiwal. (Contract Giver) (DML No. 000197). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	KO-XIME 100mg/5ml Suspension
	Composition	Each 5ml Contains; Cefixime …..100mg
	Diary No. Date of R & I & fee	Dy.No.16879 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0834712 dated 7.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cefixime 100 mg/5 mL Powder for Oral Suspension - PL 04569/1118; UK/H/2828/001/DC MHRA Approved.
	Me-too status	Fixicef Powder for oral suspension Reg. No. 080273 M/s Atco Laboratories Karachi.
	GMP status	Last GMP inspection was conducted on 16.01.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Kohinoor Industries is required. iii. Section approval letter of M/s English Pharmaceuticals is required. iv. The products approved in RRA are using trihydrate, the label of applied product does not mention the hydrate of Cefixime. Justification or correction is required is along with submission of requisite fee (Full Fee). v. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; o Dry Powder Injectable (Penicillin)

		○ Liquid ampoule Injectable (General) ○ Dry powder Lyophilized Injectable (General) ○ Large Volume Vial Injectable (General)
	Decision: Approved with following label claim; **Each 5mL contains;** **Cefixime as trihydrate equivalent to Cefixime …….100mg** • **Registration letter shall be issued after submission of fee Rs. 75,000/- vide Notification No. 7-11/2012-B&A/DRAp dated 07.05.2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**	
385	Name and address of manufacturer/ Applicant	M/s Kohinoor Industries 160/B, Small Industries Estate Sahiwal. (Contract Giver) (DML No. 000197). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	KO-XIME 200mg/5ml Suspension.
	Composition	Each 5ml Contains; Cefixime ……200mg
	Diary No. Date of R & I & fee	Dy.No.16880 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0834713 dated 7.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifiations.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cefixime 200mg/5ml for Suspension; Oral. By Alkem Labs ltd. USFDA Approved.
	Me-too status	Cefspan DS Suspension Reg. No. 024634
	GMP status	Last GMP inspection was conducted on 16.01.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Kohinoor Industries is required. iii. Section approval letter of M/s English Pharmaceuticals is required. iv. The products approved in RRA are using trihydrate, the label of applied product does not mention the hydrate of Cefixime. Justification or correction is required is along with submission of requisite fee (Full Fee). v. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; ○ Dry Powder Injectable (Penicillin) ○ Liquid ampoule Injectable (General)

		o Dry powder Lyophilized Injectable (General) o Large Volume Vial Injectable (General)
	Decision: Approved with following label claim; **Each 5mL contains;** **Cefixime as trihydrate equivalent to Cefixime …….200mg** • **Registration letter shall be issued after submission of fee Rs. 75,000/- vide Notification No. 7-11/2012-B&A/DRAp dated 07.05.2021** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**	
386	Name and address of manufacturer/ Applicant	M/s Kohinoor Industries 160/B, Small Industries Estate Sahiwal. (Contract Giver) (DML No. 000197). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	RA-D 200,000IU Injection
	Composition	Each 1ml Ampoule contains; Vitamin D3 (Cholecalciferol)……200,000IU
	Diary No. Date of R & I & fee	Dy.No.16875 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0834715 dated 7.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Vitamin D and analogues ATC Code: A11CC05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 BON 200,000 IU/1 ml solution for injection IM ampoule ANSM France Approved.
	Me-too status	Sunny D Insta Ampoule Reg. No. 063450 M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Last GMP inspection was conducted on 16.01.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Kohinoor Industries is required. iii. Section approval letter of M/s English Pharmaceuticals is required. iv. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; o Dry Powder Injectable (Penicillin) o Liquid ampoule Injectable (General) o Dry powder Lyophilized Injectable (General) o Large Volume Vial Injectable (General)

	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-202. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**	
387	Name and address of manufacturer/ Applicant	M/s Kohinoor Industries 160/B, Small Industries Estate Sahiwal. (Contract Giver) (DML No. 000197). Contract with M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore. (Contract acceptor) (DML No. 000339)
	Brand Name + Dosage Form + Strength	KO-XIME 400mg Capsule
	Composition	Each Capsule Contains; Cefixime ……400mg
	Diary No. Date of R & I & fee	Dy.No.16881 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0834714 dated 7.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Innovator's Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Suprax (Cefixime) Capsules 400mg USFDA Approved.
	Me-too status	Cefspan 400mg Capsules Reg. No. 013860 M/s Barret Hodgson Pakistan Karachi.
	GMP status	Last GMP inspection was conducted on 16.01.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s English Pharma is required. ii. Copy of DML of M/s Kohinoor Industries is required. iii. Section approval letter of M/s English Pharmaceuticals is required. iv. The products approved in RRA are using trihydrate, the label of applied product does not mention the hydrate of Cefixime. Justification or correction is required is along with submission of requisite fee (Full Fee). v. Capacity assessment of M/s English Pharmaceuticals was conducted on 14.06.2019 for following sections; o Dry Powder Injectable (Penicillin) o Liquid ampule Injectable (General) o Dry powder Lyophilized Injectable (General) o Large Volume Vial Injectable (General)
	Decision: Approved with following label claim; **Each Capsule contains;** **Cefixime as trihydrate equivalent to Cefixime …….400mg** • **Registration letter shall be issued after submission of fee Rs. 75,000/- vide Notification No. 7-11/2012-B&A/DRAp dated 07.05.2021**	

	• **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road Lahore.**	
388	Name and address of manufacturer/ Applicant	M/s Dr. Raza Pharma, 44-C, Industrial Estate, Hayatabad, Peshawar (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	RAZABACT 2.25gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……2.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.25gm
	Diary No. Date of R & I & fee	Dy.No.16938 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0803239 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 2 G/ 0.25 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0045 MHRA APPROVED.
	Me-too status	Tanzo 2.25gm Inj Reg. No. 039593 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	The panel has conducted capacity assessment of the firm, M/s Global Pharmaceuticals on 21.10.2022 for following sections and has submitted report to PE&R Division for further processing: 1. Dry Powder Injection (Cephalosporin) 2. Dry Powder Injection (Penicillin) 3. Dry Powder Injection (Carbapenem) 4. Liquid Injection Ampoule (General)
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
389	Name and address of manufacturer/ Applicant	M/s Dr. Raza Pharma, 44-C, Industrial Estate, Hayatabad, Peshawar (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	RAZABACT 4.5gram Injection (IV)
	Composition	Each Vial Contains;

		Sterile Piperacillin Sodium equivalent to Piperacillin……4.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.5gm
	Diary No. Date of R & I & fee	Dy.No.16937 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 08032240 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 4 G/ 0.50 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0046 MHRA APPROVED.
	Me-too status	Tanzo 4.5gm Inj Reg. No. 039439 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
390	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Carbapenem) Section.
	Brand Name + Dosage Form + Strength	MEPNAM INJECTION 500mg/500mg IV
	Composition	Each Vial Contains; Imipenem Monohydrate eq. to Imipenem …….. 500mg Cilastatin Sodium eq. to Colastatin …… 500mg
	Diary No. Date of R & I & fee	Dy.No.16450 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844415 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Carbapenems ATC Code: J01DH51
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP specifications.
	Pack size & Demanded Price	1's. As per SRO
	Approval status of product in Reference Regulatory Authorities	IMIPENEM/CILASTATIN 500/500MG POWDER FOR SOLUTION FOR INFUSION (IMIPENEM, CILASTATIN SODIUM) - UK/H/1409/001/DC; PL 14894/0665 MHRA APPROVED.
	Me-too status	Imclas Inj IV Reg. No. 048341 M/s Global Pharmaceuticals Islamabad.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	

	Decision: Approved. • **M/s Global shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent along with BMR of recently manufactured batches from M/s Global Pharmaceuticals, as evidence of use of the recommended diluent before issuance of Registration letter.** • **Firm shall use correct fill weight per vial considering the sodium content as per the drug substance manufacturer's claim for the commercial batches and submit BMR of recently manufactured batches from M/s Global Pharmaceuticals as evidence of correct fill weight before issuance of Registration letter.** • **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.**	
391	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Cephalosporin) Section
	Brand Name + Dosage Form + Strength	CEFSUL 1gm Injection (IV/IM)
	Composition	Each Vial Contains; Cefoperazone Sodium USP equivalent to Cefoperazone…….. 500mg Sulbactum Sodium USP equivalent to Sulbactam……..500mg
	Diary No. Date of R & I & fee	Dy.No.16452 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844417 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Global Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SULPERAZONE FOR INTRAVENOUS INJECTION 1G PDMA JAPAN APPROVED.
	Me-too status	Q-Bact 1gm Injection Reg. No. 061169 M/s High-Q International Karachi.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
392	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	CEFSUL 2gm Injection (IV/IM)

	Composition	Each Vial Contains; Cefoperazone Sodium USP equivalent to Cefoperazone …….. 1000mg Sulbactum Sodium USP equivalent to Sulbactam……..…..1000mg
	Diary No. Date of R & I & fee	Dy.No.16453 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844418 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Global Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Q-Bact 2gm Injection Reg. No. 061170 M/s High-Q International Karachi.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
393	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	CEFER 250mg Injection (IM)
	Composition	Each Vial Contains; Ceftriaxone Sodium eq. to Ceftriaxone ….. 250mg
	Diary No. Date of R & I & fee	Dy.No.16446 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844411 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	CEFTRIAXONE 250MG POWDER FOR SOLUTION FOR INJECTION - PL 24598/0006 MHRA APPROVED.
	Me-too status	Rocephin IM Inj Reg. No. 008432 M/s Martin Dow Ltd. Karachi.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	

394	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	CEFER 500mg Injection (IV)
	Composition	Each Vial Contains; Ceftriaxone Sodium eq. to Ceftriaxone …... 500mg
	Diary No. Date of R & I & fee	Dy.No.16447 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844412 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	CEFTRIAXONE 500 MG POWDER FOR SOLUTION FOR INJECTION - PL 41947/0018; UK/H/6066/001/DC MHRA APPROVED.
	Me-too status	Rocephin IV Inj Reg. No. 008435 M/s Martin Dow Ltd. Karachi.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
395	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	CEFER 500mg Injection (IM)
	Composition	Each Vial Contains; Ceftriaxone Sodium eq. to Ceftriaxone ….. 500mg
	Diary No. Date of R & I & fee	Dy.No.16448 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844413 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	CEFTRIAXONE 500 MG POWDER FOR SOLUTION FOR INJECTION - PL 41947/0018; UK/H/6066/001/DC MHRA APPROVED.
	Me-too status	Rocephin IM Inj Reg. No. 008434 M/s Martin Dow Ltd. Karachi.

	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
396	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	CEFER 1gm Injection (IV)
	Composition	Each Vial Contains; Ceftriaxone Sodium eq. to Ceftriaxone ….. 1000mg
	Diary No. Date of R & I & fee	Dy.No.16449 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844414 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	CEFTRIAXONE 1 G AND 2 G POWDER FOR SOLUTION FOR INJECTION/INFUSION - PL 41947/0019-0020; UK/H/6066/002-003/DC MHRA APPROVED.
	Me-too status	Rocephin IV Inj Reg. No. 008437 M/s Roche Ltd. Karachi.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
397	Name and address of manufacturer/ Applicant	M/s Fresh Pharmaceuticals Plot No. 7 St. no. S-6, National Industrial Zone RCCI Rawat. (Contract Giver) (DML No. 000827). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	RENAPHAS 10mEq Tablets
	Composition	Each Extended Release Tablet Contains; Potassium Citrate……10mEq (1080mg)
	Diary No. Date of R & I & fee	Dy.No.16454 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844420 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	MINERAL SUPPLEMENTS, Potassium. (Potassium citrate preparations indicated for e.g. treatment of renal tubular acidosis with calcium stones) ATC Code:A12BA02

	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's & 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Urocit-, 5mEq, 10mEq, 15mEq Extended-release tablets USFDA Approved
	Me-too status	Exocite XR 10mEq tablets Reg. No. 080827 M/s Vision Pharmaceuticals Islamabad.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility for "Tablet (general) section" of M/s Global Pharmaceuticals.	
398	Name and address of manufacturer/ Applicant	M/s Inventor Pharma, Plot No. K/196 SITE (SHW) PH-II Karachi. (Contract Giver) (DML No. 000866). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Carbapenem) Section.
	Brand Name + Dosage Form + Strength	MEROPEN INJECTION 500mg (IV)
	Composition	Each Vial Contains; Meropenem USP…….. 500mg
	Diary No. Date of R & I & fee	Dy.No.13922 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844288 dated 04.03.2019, endorsed on 06s.03.2019
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 500 MG AND 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION (MEROPENEM) - UK/H/4098/001-2/DC; PL 34985/0003-4 MHRA APPROVED.
	Me-too status	Meronem IV 500mg Injection Reg. No. 096203 M/s Pfizer Pakistan.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	i. Label claim is without consideration of hydrated form of the API. Justification or correction of label claim is required for consideration of hydrated form of API along with submission of requisite fee (full fee)
	Decision: Approved with following label claim; **"Each Vial Contains:** **Meropenem Trihydrate Eq. To Meropenem…500mg"** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021.** • **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**	

	• **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.**	
399	Name and address of manufacturer/ Applicant	M/s Inventor Pharma, Plot No. K/196 SITE (SHW) PH-II Karachi. (Contract Giver) (DML No. 000866). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Carbapenem) Section.
	Brand Name + Dosage Form + Strength	MEROPEN INJECTION 1000mg (IV)
	Composition	Each Vial Contains; Meropenem USP…….. 1gm
	Diary No. Date of R & I & fee	Dy.No.13923 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844285 dated 04.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 500 MG AND 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION (MEROPENEM) - UK/H/4098/001-2/DC; PL 34985/0003-4 MHRA APPROVED.
	Me-too status	Meronem IV 500mg Injection Reg. No. 096203 M/s Pfizer Pakistan.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	i. Label claim is without consideration of hydrated form of the API. Justification or correction of label claim is required for consideration of hydrated form of API along with submission of requisite fee (full fee)
	Decision: Approved with following label claim; **"Each Vial Contains:** **Meropenem Trihydrate Eq. To Meropenem….1gm"** • **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.**	
400	Name and address of manufacturer/ Applicant	M/s Medicraft Pharmaceutical (Pvt.) Ltd. 126-B, Industrial Estate, Hayatabad, Peshawar. (Contract Giver) (DML No. 000390). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.

	Brand Name + Dosage Form + Strength	TAZOCRAFT 2.25gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……2.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.25gm
	Diary No. Date of R & I & fee	Dy.No. 16941 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0803241 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 2 G/ 0.25 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0045 MHRA APPROVED.
	Me-too status	Tanzo 2.25gm Inj Reg. No. 039593 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
401	Name and address of manufacturer/ Applicant	M/s Medicraft Pharmaceutical (Pvt.) Ltd. 126-B, Industrial Estate, Hayatabad, Peshawar. (Contract Giver) (DML No. 000390). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	TAZOCRAFT 4.5gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……4.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.5gm
	Diary No. Date of R & I & fee	Dy.No. 16942 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0803242 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 4 G/ 0.50 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0046 MHRA APPROVED.

	Me-too status	Tanzo 4.5gm Inj Reg. No. 039439 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
402	Name and address of manufacturer/ Applicant	M/s Meditech Pharmaceuticals 15-D Industrial Estate, Hayatabad, Peshawar. (Contract Giver) (DML No.). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	MEDIBACT 2.25gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……2.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.25gm
	Diary No. Date of R & I & fee	Dy.No. 16940 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0803237 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 2 G/ 0.25 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0045 MHRA APPROVED.
	Me-too status	Tanzo 2.25gm Inj Reg. No. 039593 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	i. Copy of DML of M/s Meditech Pharma is required.
	Decision: Deferred for clarification as the DML site of M/s Meditech Pharmaceuticals has been changed to Plot No. 83-A, 83-B, Indusytrail Estate, Hayatabad, Peshawar, whereas the instant application has been applied from previous site.	
403	Name and address of manufacturer/ Applicant	M/s Meditech Pharmaceuticals 15-D Industrial Estate, Hayatabad, Peshawar. (Contract Giver) Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	MEDIBACT 4.5gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……4.0gm

		Sterile Tazobactam Sodium equivalent to Tazobactam……...0.5gm
	Diary No. Date of R & I & fee	Dy.No. 16939 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0803238 dated 05.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 4 G/ 0.50 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0046 MHRA APPROVED.
	Me-too status	Tanzo 4.5gm Inj Reg. No. 039439 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	i. Copy of DML of M/s Meditech Pharma is required.
	Decision: Deferred for clarification as the DML site of M/s Meditech Pharmaceuticals has been changed to Plot No. 83-A, 83-B, Indusytrail Estate, Hayatabad, Peshawar, whereas the instant application has been applied from previous site.	
404	Name and address of manufacturer/ Applicant	M/s Nimrall Laboratories, Plot No. 24, St. No. SS-3, Rawat Industrial Zone, Rawat. (Contract Giver) (DML No. 000611). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	PIPRAL-T 2.25gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……2.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.25gm
	Diary No. Date of R & I & fee	Dy.No.13915 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1902643 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 2 G/ 0.25 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0045 MHRA APPROVED.
	Me-too status	Tanzo 2.25gm Inj Reg. No. 039593 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.

	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
405	Name and address of manufacturer/ Applicant	M/s Nimrall Laboratories, Plot No. 24, St. No. SS-3, Rawat Industrial Zone, Rawat. (Contract Giver) (DML No. 000611). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Carbapenem) Section.
	Brand Name + Dosage Form + Strength	IMEI Injection 500mg (IV)
	Composition	Each Vial Contains; Imipenem monohydrate eq. to Imipenem …250mg Cilastatin Sodium eq. to Cilastatin ……..250mg
	Diary No. Date of R & I & fee	Dy.No.13920 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1902639 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Carbapenems ATC Code: J01DH51
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	IMIPENEM/CILASTATIN 250MG/250MG AND 500MG/500MG POWDER FOR SOLUTION FOR INFUSION - UK/H/1704/001-002/DC; PL 30306/0112-3 MHRA APPROVED.
	Me-too status	Cilnem 250mg Injection IV Reg. No. 094314 M/s Nicholas Pharma Rawat.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. • **M/s Global shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent along with BMR of recently manufactured batches from M/s Global Pharmaceuticals, as evidence of use of the recommended diluent before issuance of Registration letter.** • **Firm shall use correct fill weight per vial considering the sodium content as per the drug substance manufacturer's claim for the commercial batches and submit BMR of recently manufactured batches from M/s Global Pharmaceuticals as evidence of correct fill weight before issuance of Registration letter.** • **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.**	
406	Name and address of manufacturer/ Applicant	M/s Nimrall Laboratories, Plot No. 24, St. No. SS-3, Rawat Industrial Zone, Rawat. (Contract Giver) (DML No. 000611). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Carbapenem) Section.
	Brand Name + Dosage Form + Strength	IMEI Injection 1gm (IV)

	Composition	Each Vial Contains; Imipenem monohydrate eq. to Imipenem …500mg Cilastatin Sodium eq. to Cilastatin ……..500mg
	Diary No. Date of R & I & fee	Dy.No.13919 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1902640 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Carbapenems ATC Code: J01DH51
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	IMIPENEM/CILASTATIN 250MG/250MG AND 500MG/500MG POWDER FOR SOLUTION FOR INFUSION - UK/H/1704/001-002/DC; PL 30306/0112-3 MHRA APPROVED.
	Me-too status	Cilnem 500mg Injection IV Reg. No. 094315 M/s Nicholas Pharma Rawat.
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. • **M/s Global shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent along with BMR of recently manufactured batches from M/s Global Pharmaceuticals, as evidence of use of the recommended diluent before issuance of Registration letter.** • **Firm shall use correct fill weight per vial considering the sodium content as per the drug substance manufacturer's claim for the commercial batches and submit BMR of recently manufactured batches from M/s Global Pharmaceuticals as evidence of correct fill weight before issuance of Registration letter.** • **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.**	
407	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals, Plot No. 4, St. No. S-6, National Industrial Zone Rawat. (Contract Giver) (DML No. 000600). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	PAPRA 4.5gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……4.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.5gm
	Diary No. Date of R & I & fee	Dy.No. 16936 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1901286 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.

	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 4 G/ 0.50 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0046 MHRA APPROVED.
	Me-too status	Tanzo 4.5gm Inj Reg. No. 039439 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 03.01.2022. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
408	Name and address of manufacturer/ Applicant	M/s Treat Pharmaceutical Industry (Pvt.) Ltd. A-37 Small Industrial Estate Township, Kohat Road Bannu. (Contract Giver) (DML No. 000352). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.
	Brand Name + Dosage Form + Strength	TREATBACT 2.25gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……2.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.25gm
	Diary No. Date of R & I & fee	Dy.No.16418 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0622504 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 2 G/ 0.25 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0045 MHRA APPROVED.
	Me-too status	Tanzo 2.25gm Inj Reg. No. 039593 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
409	Name and address of manufacturer/ Applicant	M/s Winilton Pharmaceutical (Pvt.) Ltd. , Plot No. 45, St. No. S-5, Rawat Industrial Zone, Rawat. (Contract Giver) (DML No. 000721). Contract with M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad. (Contract acceptor) (DML No. 000417) Dry Powder Injection (Penicillin) Section.

	Brand Name + Dosage Form + Strength	PIPRAWIN 4.5gram Injection (IV)
	Composition	Each Vial Contains; Sterile Piperacillin Sodium equivalent to Piperacillin……5.0gm Sterile Tazobactam Sodium equivalent to Tazobactam……...0.5gm
	Diary No. Date of R & I & fee	Dy.No.16392 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1902631 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 4 G/ 0.50 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0046 MHRA APPROVED.
	Me-too status	Tanzo 4.5gm Inj Reg. No. 039439 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 19.11.2021. GMP Status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.	
410	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	BETACAM 20mg Tablets
	Composition	Each Dispersible Tablet Contains; Piroxicam beta cyclodextrin……20mg
	Diary No. Date of R & I & fee	Dy.No.169715 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740093 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Oxicams ATC Code: M01AC01
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	Manufacturers Specifications.
	Pack size & Demanded Price	20's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	BREXIN 20 MG EFFERVESCENT TABLET ANSM FRANCE APPROVED.
	Me-too status	Straza Tablet Reg. No. 096316 M/s Asian Continental Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required.

		ii. The strength of active with complex combined is mentioned as 20mg. The label claim needs to be revised for only strength of active (as complex) along with submission of requisite fee (Full Fee). iii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **"Each Dispersible Tablet Contains;** **Piroxicam beta cyclodextrin Eq. to Piroxicam……20mg"** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021 for correction/pre-approval change of the composition of product.** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
411	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	CEFABACT PLUS 1g Injection (IV/IM)
	Composition	Each Vial Contains; Cefoperazone Sodium USP……..500mg Sulbactam Sodium USP……...500mg
	Diary No. Date of R & I & fee	Dy.No.16977 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740082 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor. ATC Code: J01DD62
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Sulperazon Injection, Pfizer Inc. PMDA Approved
	Me-too status	2Sum Injection 1g Reg. No. 047002 M/s Sami Pharmaceuticals
	GMP status	Last inspection conducted on 10.01.2018

	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. Evidence of approval of applied product in RRA is required. iii. The reference product contains Cefoperazone As Sodium and Sulbactam As Sodium (0.5g each) while the applied product contains Cefoperazone Sodium and Salbactum Sodium (0.5g each), clarify or otherwise submit revised formulation with correct equivalency factor along with the submission of requisite fee (Full Fee). iv. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **"Each Vial Contains;** **Cefoperazone as Sodium USP……..500mg** **Sulbactam as Sodium USP……...500mg "** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
412	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	CEFABACT PLUS 2g Injection (IM/IV)
	Composition	Each Vial Contains; Cefoperazone Sodium USP……..1000mg Sulbactam Sodium USP……...1000mg
	Diary No. Date of R & I & fee	Dy.No.16978 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740083 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins, cefoperazone and beta-lactamase inhibitor.

		ATC Code: J01DD62
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	2Sum Injection 2g Reg. No. 047003 M/s Healthtek Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. i. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **Each Vial Contains;** **Cefoperazone as Sodium USP……..1000mg** **Sulbactam as Sodium USP……...1000mg** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
413	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	CEFTIMAX 250mg Injection (IM/IV)
	Composition	Each Vial Contains; Ceftriaxone Sodium……250mg
	Diary No. Date of R & I & fee	Dy.No.16981 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740074 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.

	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Zetox 250mg Injection Reg. No. 053144 M/s Lahore Pharma.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. The reference product contains Ceftriaxone as Sodium and while the applied product contains Ceftriaxone Sodium. Clarify or otherwise submit revised formulation with correct equivalency factor along with the submission of requisite fee (Full Fee). ii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **"Each Vial Contains;** **Ceftriaxone as Sodium……250mg"** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
414	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	CEFTIMAX 200mg Injection (IM/IV)
	Composition	Each Vial Contains; Ceftriaxone Sodium……500mg
	Diary No. Date of R & I & fee	Dy.No.16982 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740085 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins.

		ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Zetox 500mg Injection Reg. No. 053145 M/s Lahore Pharma.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. The reference product contains Ceftriaxone as Sodium and while the applied product contains Ceftriaxone Sodium. Clarify or otherwise submit revised formulation with correct equivalency factor along with the submission of requisite fee (Full Fee). iii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **"Each Vial Contains;** **Ceftriaxone as Sodium……500mg"** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
415	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	CEFTIMAX 1g Injection (IV/IM)
	Composition	Each Vial Contains; Ceftriaxone Sodium USP……1000mg

	Diary No. Date of R & I & fee	Dy.No.16983 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740086 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1s, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Rocephin IV/IM Injection 1gm Reg. No. 007014 M/s Martin Dow Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. The reference product contains Ceftriaxone as Sodium and while the applied product contains Ceftriaxone Sodium. Clarify or otherwise submit revised formulation with correct equivalency factor along with the submission of requisite fee (Full Fee). iv. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **Each Vial Contains;** **Ceftriaxone as Sodium USP……1000mg** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
416	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)

	Brand Name + Dosage Form + Strength	KETOCARE 30mg/1ml Injection (IV)
	Composition	Each 1ml Ampoule Contains; Ketorolac Trometamol BP……30mg
	Diary No. Date of R & I & fee	Dy.No.16973 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740092 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Acetic acid derivatives and related substances. ATC Code: M01AB15
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5 ampoules of 1ml each. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/ml Solution for Injection MHRA Approved.
	Me-too status	Cadlec 30mg/ml Injection IM/IV Reg. No. 095892 M/s Brookes Pharma Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. v. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section.
	Decision: Deferred for clarification of sterilisation method used for the applied formulation.	
417	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	MECAL 500mcg/ml Injection (IM)
	Composition	Each 1ml Ampoule Contains; Mecobalamine ……500mcg
	Diary No. Date of R & I & fee	Dy.No.16972 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740091 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues). ATC Code: B03BA05
	Type of Form	Form- 5 (Contract Application)

	Finished product Specification	Manufacturers Specifications.
	Pack size & Demanded Price	10 ampoules of 1ml each. As per SRO.
	Approval status of product in Reference Regulatory Authorities	METHYCOBAL 500µginjection PDMA Japan Approved.
	Me-too status	Mecomed 500mcg Reg. No. 041670 M/s Global Pharma Islamabad.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. vi. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section.
	Decision: Approved with Innovator's specifications. • **Registration letter shall be issued after submission of fee Rs. 7,500/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
418	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	MEFLOX 400mg/250ml Infusion
	Composition	Each ml contains; Moxifloxacin HCl……..1.6mg
	Diary No. Date of R & I & fee	Dy.No.16979 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740088 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	250ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	MOXIFLOXACIN 400 MG/250 ML SOLUTION FOR INFUSION - PL 24598/0022; UK/H/4829/001/DC MHRA APPROVED.
	Me-too status	Avelox Infusion Reg. No. 109733 M/s Bayer Pakistan Kot Lakhpat.

	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. In pack size, 2 volumes are mentioned (100ml and 250ml). By changing volume amount of drug per infusion changes so different volume needs to be applied separately. iii. The strength in label claim is of combined drug and its HCl. The label needs to be revised to mention equivalent strength of drug as its HCl salt. Requisite for correction is also required (Full Fee)
	Decision: Deferred for submission of correct Form-5 along with correct details of applied product and applicable full fee as per notification No. F.7-11/2012-B&A/DRAP dated 07.05.2021.	
419	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	TRICEF 400mg Capsules
	Composition	Each Capsule Contains; Cefixime trihydrate…….. 400mg
	Diary No. Date of R & I & fee	Dy.No.16986 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740080 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SUPRAX (CEFIXIME) CAPSULES 400MG USFDA APPROVED.
	Me-too status	Cefspan 400mg Capsules Reg. No. 013860 M/s Barret Hodgson Pakistan Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. The strength of applied product is 400mg with hydrate included. The strength of approved products in RRA and as me-too have strength of active 400 mg as trihydrate. Correction is required along with submission of requisite fee (Full Fee) vii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin)

		• Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **Each Capsule Contains;** **Cefixime trihydrate equivalent to Cefixime…….. 400mg** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
420	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	TRICEF 100mg Suspension
	Composition	Each 5ml Contains; Cefixime Trihydrate…..100mg
	Diary No. Date of R & I & fee	Dy.No.16984 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740078 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	CEFIXIME 100 MG/5 ML POWDER FOR ORAL SUSPENSION - PL 04569/1118; UK/H/2828/001/DC MHRA APPROVED.
	Me-too status	Fixicef Powder for oral suspension Reg. No. 080273 M/s Atco Laboratories Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. The strength of applied product is 100mg/5ml with hydrate included. The strength of approved products in RRA and as me-too have strength of active 100mg/5ml as trihydrate. Correction is required along with submission of requisite fee (Full Fee) viii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin)

		• Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **"Each 5ml Contains;** **Cefixime Trihydrate equivalent to Cefixime …..100mg"** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
421	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	TRICEF 200mg Suspension.
	Composition	Each 5ml Contains; Cefixime trihydrate ……..200mg
	Diary No. Date of R & I & fee	Dy.No.16985 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740079 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Third-generation cephalosporins ATC Code: J01DD08
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities	CEFIXIME 200MG/5ML FOR SUSPENSION; ORAL. BY ALKEM LABS LTD. USFDA APPROVED.
	Me-too status	Cefspan DS Suspension Reg. No. 024634
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. The strength of applied product is 200mg/5ml with hydrate included. The strength of approved products in RRA and as me-too have strength of active 200mg/5ml as trihydrate. Correction is required along with submission of requisite fee (Full Fee) ix. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General),

		• Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with following label claim; **"Each 5ml Contains;** **Cefixime Trihydrate equivalent to Cefixime …….. 200mg"** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
422	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	Calcifer 5mg/1ml Injection (IM)
	Composition	Each 1ml Ampoule Contains; Cholecalciferol BP……..5mg
	Diary No. Date of R & I & fee	Dy.No.16974 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740090 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Vitamin D and analogues ATC Code: A11CC05
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 BON 200,000 IU/1 ML SOLUTION FOR INJECTION IM AMPOULE ANSM FRANCE APPROVED.
	Me-too status	Sunny D Insta Ampoule Reg. No. 063450 M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. x. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board Wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin)

		• Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section
	Decision: Approved with innovator's specifications. • **Registration letter shall be issued after submission of fee Rs. 75,00/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
423	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	MEFLOX 400mg Tablet
	Composition	Each Film Coated Tablet Contains; Moxifloxacin HCl……. 400mg
	Diary No. Date of R & I & fee	Dy.No.16980 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740087 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5's and 10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	KIMOKS 400 MG FILM-COATED TABLETS (MOXIFLOXACIN HYDROCHLORIDE) - PL 34088/0047; UK/H/6473/001/DC MHRA APPROVED.
	Me-too status	Avelox Tablets Reg. No. 024653 M/s Bayer Pakistan Ltd Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. The applied strength/formulation is of combined drug and its HCl. The label needs to be revised to mention equivalent strength of drug as its HCl salt. Requisite for correction is also required (Full Fee). iii.
	Decision: Approved with following label claim; **"Each Film Coated Tablet Contains;** **Moxifloxacin as HCl……. 400mg"** • **Registration letter shall be issued after submission of fee Rs. 75,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021** • **As decided in 317th meeting of Registration Board, M/s Medisave Pharmaceuticals shall submit compliance report from the contract manufacturer i.e, for further increase in testing capacity especially HPLC, microbiological testing etc before issuance of registration letter.**	
424	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with

		M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	Hb-Plus 100mg/5ml Injection (IV)
	Composition	Each 5ml Ampoule Contains; Iron Sucrose equivalent to Elemental Iron……100mg
	Diary No. Date of R & I & fee	Dy.No.16976 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740089 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Iron, parenteral preparations ATC Code: B03AC
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5 ampoules of 5ml each. As per SRO.
	Approval status of product in Reference Regulatory Authorities	SUCROFER 20 MG IRON/ML, SOLUTION FOR INJECTION /INFUSION (IRON SUCROSE) - UK/H/6369/001/DC; PL 20568/0083 MHRA APPROVED.
	Me-too status	Venofer IV Injection Reg. No. 085031 M/s OBS Pakistan Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board, wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section.
	Decision: Deferred for evidence of availability of atomic absorption spectrophotometer as required by the USP monograph.	
425	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	COARTEM Tablet 20mg/120mg
	Composition	Each Tablet Contains: Artemether…….20mg Lumefantrine…….120mg
	Diary No. Date of R & I & fee	Dy. No. 13342 dated 07-03-2019. Fee paid Rs. 20000/- vide Slip No. 0846642 dated 07.03.2019
	Pharmacological Group	Artemisinin and derivatives, combinations

		ATC Code: P01BF01
	Type of Form	Form 5
	Finished product Specification	Innovators Specifications.
	Pack size & Demanded Price	2×8's, Rs. 240/-
	Approval status of product in Reference Regulatory Authorities	Artemether and Lumefantrine 20mg/120mg tablet approved by WHO Pre-qualified product list.
	Me-too status	Arther Tablets 20mg/120mg Reg. No. 049292 M/s Focus & Rulz Islamabad.
	GMP status	
	Remarks of the Evaluator	i. Updated GMP status is required. ii. Applied product is available in International Pharmacopoeia and firm has applied innovators specifications. Specifications shall be changed along with submission of requisite fee.
	Decision: Approved with IP Specifications. Registration letter shall be issued after submission of fee Rs. 7500/- as per Notification No. 7-11/2012-B&A dated 07.05.2021 and submission of GMP inspection report/ certificate within last 3 years by QA&LT Division.	
426	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	COARTEM FORTE Tablet 80mg/480mg
	Composition	Each Tablet Contains: Artemether……80mg Lumefantrine…….480mg
	Diary No. Date of R & I & fee	Dy. No. 13344 dated 07-03-2019. Fee paid Rs. 20000/- vide Slip No. 0846644 dated 07.03.2019
	Pharmacological Group	Artemisinin and derivatives, combinations ATC Code: P01BF01
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	6's, Rs. 330/-
	Approval status of product in Reference Regulatory Authorities	WHO Approved formulation
	Me-too status	Artiavant Tablet 80/480mg Reg. No. 102981 M/s Avant Pharmaceuticals (Pvt) Ltd Balochistan
	GMP status	
	Remarks of the Evaluator	i. Updated GMP status is required. ii. Applied product is available in International Pharmacopoeia and firm has applied innovators specifications. Specifications shall be changed along with submission of requisite fee.
	Decision: Approved with IP Specifications. **Registration letter shall be issued after submission of fee Rs. 7500/- as per Notification No. 7-11/2012-B&A dated 07.05.2021 and submission of latest GMP inspection report/ certificate within last 3 years by QA&LT Division.**	
427	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Arrefloxacin 250mg tablet
	Composition	Each Film Coated Tablet contains:

		Levofloxacin as hemihydrate……250mg
	Diary No. Date of R & I & fee	Dy. No. 13366 dated 07-03-2022. Fee paid Rs. 20000/- vide slip No. 1900443 dated 07.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA12
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Ipca Laboratories UK Limited MHRA Approved.
	Me-too status	Brodin 250mg tablets Reg. No. 024610 M/s Werrick Pharmaceuticals.
	GMP status	
	Remarks of the Evaluator	i. Valid GMP certificate/ report is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP inspection report/ certificate within last 3 years by QA&LT Division.	
428	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Arrefon Tablet 5mg
	Composition	Each sugar coated tablet contains: Bisacodyl…….5mg
	Diary No. Date of R & I & fee	Dy. No. 13413 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0785046 dated 07.03.2019.
	Pharmacological Group	Contact laxatives ATC Code: A06AB02
	Type of Form	Form 5
	Finished product Specification	B.P Specifications.
	Pack size & Demanded Price	10×10's
	Approval status of product in Reference Regulatory Authorities	Bisacodyl gastro resistant tablet 5mg MHRA Approved.
	Me-too status	Bisacodyl 5mg tablet of M/s SAMI (Reg. # 002981)
	GMP status	
	Remarks of the Evaluator	i. Updated GMP status is required. ii. The product approved in RRA is gastro-resistant formulation, whereas applied formulation is sugar coated. Change of formulation is required along with submission of requisite fee.
	Decision: Approved with following label claim; **Each gastro-resistant tablet contains:** **Bisacodyl…….5mg** **Registration letter shall be issued after submission of fee Rs. 7500/- as per Notification No. 7-11/2012-B&A dated 07.05.2021 and submission of latest GMP inspection report/ certificate within last 3 years by QA&LT Division.**	
429	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Capsule Section (General)
	Brand Name + Dosage Form + Strength	Arreval 75mg Capsule
	Composition	Each Extended release capsule contains: Venlafaxine Hydrochloride pellet 33% eq. to venlafaxine……..75mg

	Diary No. Date of R & I & fee	Dy. No. 13411 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0785044 dated 07.03.2019
	Pharmacological Group	ANTIDEPRESSANTS. ATC Code: N06AX16
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	2×7's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Venlafaxine Hydrochloride extended release capsule (37.5mg, 75mg, 150mg) by M/s TEVA, USFDA Approved.
	Me-too status	Venflax XR 75mg capsule of M/s Regal Pharmaceuticals
	GMP status	Not Provided
	Remarks of the Evaluator	i. Updated GMP status is required. ii. Source of pellets is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division, source of pellets and applicable fee as per notification vide No. F.7-11/2012-B&A/DRAP dated 07.05.2021	
430	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Capsule Section (General)
	Brand Name + Dosage Form + Strength	Arreval 150mg Capsule
	Composition	Each Extended release capsule contains: Venlafaxine Hydrochloride pellet 33% eq. to venlafaxine……..150mg
	Diary No. Date of R & I & fee	Dy. No. 13412 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0785045 dated 07.03.2019.
	Pharmacological Group	ANTIDEPRESSANTS. ATC Code: N06AX16
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	2×7's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Venlafaxine Hydrochloride extended release capsule (37.5mg, 75mg, 150mg) by M/s TEVA, USFDA Approved.
	Me-too status	Zentel Suspension Reg. No. 006730 M/s Glaxo Smith Kline Karachi.
	GMP status	Not Provided
	Remarks of the Evaluator	i. Updated GMP status is required. ii. Source of pellets is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division, source of pellets and applicable fee as per notification vide No. F.7-11/2012-B&A/DRAP dated 07.05.2021	
431	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. . (DML No. 000846). Oral Liquid Section (General)
	Brand Name + Dosage Form + Strength	Arrezole 100mg Suspension
	Composition	Each 5ml contains: Albendazole…….100mg
	Diary No. Date of R & I & fee	Dy. No. 13334; dated 07-03-2019; Fee Paid 20000/- vide Slip No. 0846634 dated 07.03.2019.
	Pharmacological Group	ANTINEMATODAL AGENTS, Benzimidazole derivatives.

		ATC Code: P02CA03
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10ml, Rs. 18.65/-
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Benda by M/s Pharmedic
	GMP status	Vaild GMP certificate is not provided.
	Remarks of the Evaluator	i. Updated GMP status is required. ii. Section approval letter is required. iii. Evidence of approval in RRA is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
432	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	B-Six Tablet 50mg
	Composition	Each tablet contains: Pyridoxine Hydrochloride…….50mg
	Diary No. Date of R & I & fee	Dy. No. 13331; dated 07-03-2019; Fee Paid Rs. 20000/- vide Slip No. 0825421 dated 07.03.2019
	Pharmacological Group	Other plain vitamin preparations. ATC code: A11HA02
	Type of Form	Form-5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	2×10's
	Approval status of product in Reference Regulatory Authorities	Pyridoxine hydrochloride 50mg tablets MHRA Approved
	Me-too status	Pyro-6 Tablet Reg. No. 028861 M/s Medera Pharmaceuticals Islamabad.
	GMP status	
	Remarks of the Evaluator	i. Updated GMP Status is required. ii. The upper tolerable limit of Vitamin B6 (pyridoxine) is 100 mg for adults.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
433	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Cinpro 1mg tablet
	Composition	Each tablet contains: Cinitapride hydrogen tartrate eq. to cinitapride……..1mg
	Diary No. Date of R & I & fee	Dy. No. 13323 dated 07-03-2019; Fee Paid Rs. 20000/- vide Slip No. 0825413 dated 07.03.2019.
	Pharmacological Group	Gastro-prokinetic, propulsive ATC Code: A03FA08
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	10's, Rs. 175/-
	Approval status of product in Reference Regulatory Authorities	Cidine 1mg tablet CIMA Spain Approved.
	Me-too status	Cinita Tablet Reg. No. 061706.

		M/s Getz Pharma (Pvt) Ltd. Karachi.
	GMP status	Valid GMP certificate is not provided.
	Remarks of the Evaluator	i. Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
434	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Arrexan Tablet 550mg
	Composition	Each film coated tablet contains: Rifaximin……550mg
	Diary No. Date of R & I & fee	Dy. No. 13352; dated 07-03-2019; Fee Paid Rs.20000/- vide slip No. 0588338 dated 07.03.2019
	Pharmacological Group	INTESTINAL ANTIINFECTIVES, Antibiotics ATC Code: A07AA11
	Type of Form	Form-5
	Finished product Specification	Innovator's Specifications.
	Pack size & Demanded Price	10's, as per SRO
	Approval status of product in Reference Regulatory Authorities	XIFAXAN Tablets by SALIX PHARMA (USFDA Approved)
	Me-too status	Nixaf 550mg tablet Reg. No. 073700. M/s Sami Pharmaceuticals Karachi
	GMP status	
	Remarks of the Evaluator	i. Updated GMP Status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
435	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Arrewarf 5mg Tablet
	Composition	Each tablet contains: Warfarin Sodium…….5mg
	Diary No. Date of R & I & fee	Dy. No. 13414; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0845202 dated 07.03.2019
	Pharmacological Group	Vitamin K antagonists ATC Code; B01AA03
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	10×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Warfarin Sodium 5mg FDA Approved.
	Me-too status	Warfin 5mg tablet Reg. No. 018670. M/s Shaigan Pharmaceuticals.
	GMP status	
	Remarks of the Evaluator	Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
436	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Arrecast 10mg tablet

	Composition	Each film coated tablet contains: Montelukast Sodium…….10mg
	Diary No. Date of R & I & fee	Dy. No. 13315 dated 07-03-2019; Fee paid 20000/- vide slip No. 0825405 dated 07.03.2019
	Pharmacological Group	Leukotriene receptor antagonists ATC Code: R03DC03
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	14's, as per SRO.
	Approval status of product in Reference Regulatory Authorities	Montelukast film coated 10mg MHRA Approved
	Me-too status	Montiget 10mg tablet Reg. No. 034838 M/s Getz Pharmaceuticals.
	GMP status	
	Remarks of the Evaluator	Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division and correction of salt form alongwith requisite fee.	
437	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Rion 2mg tablet
	Composition	Each film coated tablet contains: Risperidone……2mg
	Diary No. Date of R & I & fee	Dy. No. 13340 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0846640 dated 07.03.2019.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	RISPERIDONE 0.5MG, 1MG, 2MG, 3MG, 4MG AND 6MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Risperiscot Flash Tablet 2mg Reg. No. 046253 M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Valid GMP certificate is not provided.
	Remarks of the Evaluator	Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
438	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Rion 4mg tablet
	Composition	Each film coated tablet contains: Risperidone……4mg
	Diary No. Date of R & I & fee	Dy. No. 13341 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0846641 dated 07.03.2019.
	Pharmacological Group	Other antipsychotics ATC Code: N05AX08
	Type of Form	Form 5
	Finished product Specification	USP Specifications.

	Pack size & Demanded Price	5×6's, As per SRO
	Approval status of product in Reference Regulatory Authorities	RISPERIDONE 0.5MG, 1MG, 2MG, 3MG, 4MG AND 6MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Risperiscot Flash Tablet 4mg Reg. No. 046255 M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Valid GMP certificate is not provided.
	Remarks of the Evaluator	Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
439	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	B-HISTINE 8mg Tablet
	Composition	Each Tablet Contains; Betahistine dihydrochloride …. 8 mg
	Diary No. Date of R & I & fee	Dy. No. 13326 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825416 dated 07.03.2019.
	Pharmacological Group	Antivertigo preparations. ATC Code: N07CA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	3x10's. as per SRO
	Approval status of product in Reference Regulatory Authorities	Betahistine Dihydrochloride 8 mg, 16 mg and 24 mg Tablets MHRA Approved.
	Me-too status	Dowbet Tablet 8 mg. Reg. No. 107871 M/s Martin Dow Ltd Karachi.
	GMP status	
	Remarks of the Evaluator	Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
440	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	B-HISTINE 24mg Tablet
	Composition	Each Tablet Contains; Betahistine dihydrochloride …. 24 mg
	Diary No. Date of R & I & fee	Dy. No. 13328 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825418 dated 07.03.2019.
	Pharmacological Group	Antivertigo preparations. ATC Code: N07CA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	3x10's. as per SRO
	Approval status of product in Reference Regulatory Authorities	Betahistine Dihydrochloride 8 mg, 16 mg and 24 mg Tablets MHRA Approved.
	Me-too status	Dowbet Tablet 24 mg. Reg. No. 107869 M/s Martin Dow Ltd Karachi.
	GMP status	
	Remarks of the Evaluator	Updated GMP status is required.

	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
441	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Niclosan 500mg Chewable Tablet
	Composition	Each Chewable Tablet Contains; Niclosamide……. 500 mg
	Diary No. Date of R & I & fee	Dy. No. 13325 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825415 dated 07.03.2019.
	Pharmacological Group	ANTICESTODALS, Salicylic acid derivatives. ATC Code: P02DA01
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	4's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Mesan Tablets Reg. No. 018668 M/s shaigan Pharmaceuticals Rawalpindi.
	GMP status	
	Remarks of the Evaluator	**i.** Updated GMP status is required. **ii.** Evidence of approval of applied product in RRA is required. The evidence provided is discontinued by FDA.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
442	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	NEBILOL 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains; Nebivolol …….. 2.5 mg
	Diary No. Date of R & I & fee	Dy. No. 13337 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0846637 dated 07.03.2019.
	Pharmacological Group	Beta blocking agents, selective. ATC Code: C07AB12
	Type of Form	Form 5
	Finished product Specification	Innovators Specifications.
	Pack size & Demanded Price	1x14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Nebivolol 2.5 mg Tablets MHRA Approved
	Me-too status	Neobiv 2.5mg Tablet Reg. No. 099198 M/s ARP (Pvt.) Ltd. Rawat.
	GMP status	
	Remarks of the Evaluator	i. Updated GMP status is required. ii. The Nebivolol is as hydrochloride salt. The label claim is required to be changed accordingly along with submission of requisite fee (full fee). iii. The innovator product is not film coated. Justification or change is required.

	Decision: Approved with following label claim; **Each Tablet Contains;** **Nebivolol HCl equivalent to Nebivolol …….. 2.5 mg** **Registration letter shall be issued after submission of fee Rs. 30000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021 and submission of latest GMP inspection report/ certificate within last 3 years by QA&LT Division.**	
443	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	ALCETAZINE 5mg Tablet
	Composition	Each Film Coated tablet contains; Levocetirizine Dihydrochloride …….. 5 mg
	Diary No. Date of R & I & fee	Dy. No. 13332 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825422 dated 07.03.2019.
	Pharmacological Group	ANTIHISTAMINES FOR SYSTEMIC USE, Piperazine derivatives. ATC Code: R06AE09
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	3x10's
	Approval status of product in Reference Regulatory Authorities	Levocetirizine Dihydrochloride 5 mg Film-coated Tablets MHRA Approved.
	Me-too status	T-Day Tablet 5 mg Reg. No. 083964 M/s GlaxoSmithKline Petaro Roard.
	GMP status	
	Remarks of the Evaluator	Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
444	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	ARRESTAT 80mg Tablet
	Composition	Each Film Coated Tablet Contains; Febuxostat …… 80mg
	Diary No. Date of R & I & fee	Dy. No. 13333 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0846633 dated 07.03.2019.
	Pharmacological Group	Preparations inhibiting uric acid production, ATC Code: M04AA03.
	Type of Form	Form 5
	Finished product Specification	Innovators Specifications.
	Pack size & Demanded Price	3x10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Febuxostat 80mg, 120mg Film coated Tablets (febuxostat hemihydrate) MHRA Approved.
	Me-too status	Febast 80mg Tablets Reg. No. 087606 M/s Biolabs (Pvt) Ltd Islamabad.
	GMP status	
	Remarks of the Evaluator	i. Updated GMP status is required. ii. The innovators product contains febuxostat as hemihydrate. Label needs to be corrected accordingly along with submission of requisite fee (full fee).

	Decision: Approved with following label claim; **Each Film Coated Tablet Contains;** **Febuxostat as hemihydrate…… 80mg** **Registration letter shall be issued after submission of fee Rs. 30,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021 and submission of latest GMP inspection report/ certificate within last 3 years by QA&LT Division.**	
445	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	ARRETAC 150mg Tablet
	Composition	Each Film Coated Tablet Contains; Ranitidine as Hydrochloride…… 150 mg
	Diary No. Date of R & I & fee	Dy. No. 13353 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0588339 dated 07.03.2019.
	Pharmacological Group	H2-receptor antagonists. ATC Code: A02BA02
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's, as per SRO.
	Approval status of product in Reference Regulatory Authorities	MAR-RANITIDINE, Ranitidine Tablets, USP 150 mg & 300 mg ranitidine (as ranitidine hydrochloride) Health Canada Approved.
	Me-too status	Zantac 150mg Reg. No. 006520 M/s Glaxo Smith Kline Pakistan Karachi.
	GMP status	
	Remarks of the Evaluator	The Registration Board in its 294th meeting had decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products.	
446	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Oral Liquid Section (General)
	Brand Name + Dosage Form + Strength	LORIN 5mg Syrup
	Composition	Each 5 ml Contains; Loratadine …….5 mg
	Diary No. Date of R & I & fee	Dy. No. 13321 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825411 dated 07.03.2019.
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX13
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60 ml, as per SRO.
	Approval status of product in Reference Regulatory Authorities	Loratadine 5mg/5ml Oral Solution MHRA Approved.
	Me-too status	Softin Syrup Reg. No. 024780 M/s Werrick Pharmaceuticals Islamabad.
	GMP status	
	Remarks of the Evaluator	i. Updated GMP status is required. ii. Label claim of tablet is given instead of oral liquid. Revised label claim is required along with requisite fee (Full fee).

		iii. Section approval letter is required.
	Decision: Approved with following label claim; **Each 5 ml Contains;** **Loratadine …….5 mg** **Registration letter shall be issued after submission of fee Rs. 30,000/- as per Notification No. 7-11/2012-B&A dated 07.05.2021 and submission of latest GMP inspection report/ certificate within last 3 years by QA&LT Division.**	
447	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	OSICARE Tablet 630 mg
	Composition	Each Tablet Contains; Activated Attapulgite……..630mg
	Diary No. Date of R & I & fee	Dy. No. 13330 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825420 dated 07.03.2019.
	Pharmacological Group	Other intestinal adsorbents. ATC Code: A07BC04
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications.
	Pack size & Demanded Price	100's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Not provided
	Me-too status	Not provided.
	GMP status	
	Remarks of the Evaluator	i. Updated GMP status is required. ii. Evidence of RRA approval required. iii. Evidence of me-too is required.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
448	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	ROVASTATIN 5mg Tablet
	Composition	Each Film Coated Tablet Contains; Rosuvastatin Calcium equivalent to Rosuvastatin……..5mg.
	Diary No. Date of R & I & fee	Dy. No. 13316 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825406 dated 07.03.2019.
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA07
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications.
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ropuido 5 mg film-coated tablets. MHRA Approved.
	Me-too status	Rovista Tablet 5mg, Reg. No. 044043 M/s Getz Pharma Karachi.
	GMP status	
	Remarks of the Evaluator	Updated GMP status is required.

	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
449	Name and address of manufacturer/ Applicant	M/s Arreta Pharmaceuticals (pvt) Ltd. Plot no. 13, Street No. N-5, RCCI, Industrial Estate, Rawalpindi. (DML No. 000846). Tablet Section (General)
	Brand Name + Dosage Form + Strength	ROVASTATIN 20mg Tablet
	Composition	Each Film Coated Tablet Contains; Rosuvastatin Calcium equivalent to Rosuvastatin……..20mg.
	Diary No. Date of R & I & fee	Dy. No. 13318 dated 07-03-2019. Fee paid Rs. 20000/- vide slip No. 0825408 dated 07.03.2019.
	Pharmacological Group	HMG CoA reductase inhibitors. ATC Code: C10AA07
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications.
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Rosuvastatin 20 mg film-coated tablets. MHRA Approved.
	Me-too status	Rovista Tablet 20mg, Reg. No. 044045 M/s Getz Pharma Karachi.
	GMP status	
	Remarks of the Evaluator	Updated GMP status is required.
	Decision: Approved. Registration letter shall be issued after submission of updated GMP status within last 3 years by QA&LT Division.	
450	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Co-Locor tablet 100mg/25mg
	Composition	Each film coated tablet contains: Losartan Potassium……100mg Hydrochlorthiazide……25mg
	Diary No. Date of R & I & fee	Dy. No. 143578; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829858 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Angiotensin II antagonist & Diuretics ATC Code: C09DA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cozaar Comp 100 mg/25 mg film-coated tablets MHRA Approved.
	Me-too status	Co-Eziday tablet Reg. No. 056104 M/s Werrick Pharmaceuticals.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
451	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML No. 00565) Oral Liquid (General) Section.
	Brand Name + Dosage Form + Strength	Arilac Syrup
	Composition	Each 5ml contains:

		Lactulose……..3.335g
	Diary No. Date of R & I & fee	Dy. No. 14354; dated 07-03-2019; fee paid Rs. 20000/- vide slip no. 0829854 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Osmotically acting laxatives. ATC Code: A06AD11
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Lactulose 3.3g/5ml Oral Solution MHRA Approved.
	Me-too status	Duphalac Syrup Reg. No. 006655 M/s Abbott Laboratories
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Firm shall submit documents for source of Lactulose along with GMP certificate, COA, stability studies of three batches & differential fee (in case of import). .	
452	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Capsule Section (General)
	Brand Name + Dosage Form + Strength	Isotor Capsule 10mg
	Composition	Each capsule contains: Isotretnoin……10mg
	Diary No. Date of R & I & fee	Dy. No. 14371; dated 07-03-2019; Fee paid Rs. 20000/- Vide Slip No. 0829871 dated 04.03.2019. Endorsed on 06.03.2019.
	Pharmacological Group	Retinoids for treatment of acne ATC Code: D10BA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Absorica (isotretinoin) Capsules, 10 mg, 20 mg, 30 mg, and 40 mg USFDA Approved.
	Me-too status	Isonex capsule 10mg Reg. No. 060799 M/s Shrooq Pharma
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB, in light of the Notifdication No. 320-DRB/ 2022(PE&R) dated 17th October 2022.	
453	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Capsule Section (General)
	Brand Name + Dosage Form + Strength	Isotor Capsule 20mg
	Composition	Each capsule contains: Isotretnoin……20mg
	Diary No. Date of R & I & fee	Dy. No. 14377; dated 07-03-2019; Fee paid Rs. 20000/- Vide Slip No. 0829883 dated 04.03.2019. Endorsed on 06.03.2019.

	Pharmacological Group	Retinoids for treatment of acne ATC Code: D10BA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Absorica (isotretinoin) Capsules, 10 mg, 20 mg, 30 mg, and 40 mg USFDA Approved.
	Me-too status	Isonex capsule 20mg Reg. No. 060798 M/s Shrooq Pharma
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB, in light of the Notifdication No. 320-DRB/ 2022(PE&R) dated 17th October 2022.	
454	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Averon tablet 24mg
	Composition	Each tablet contains: Ondansetron Hydrochloride Dihydrate eq. to Ondansetron ……. 24mg
	Diary No. Date of R & I & fee	Dy. No. 14390; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0832334 dated 06.03.2019
	Pharmacological Group	Antiemetic (5-HT3 receptor antagonist) ATC Code: A04AA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified for 24 mg strength.
	Me-too status	Could not be verified for 24 mg strength.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	i. The evidence of RRA approval (Zofran 24mg) is discontinued. Valid evidence of RRA approval is required. ii. Evidence of me-too product is required having strength of 24mg.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
455	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Aricort Tablet 5mg
	Composition	Each tablet contains: Prednisolone……5mg
	Diary No. Date of R & I & fee	Dy. No. 14405; dated 7-03-2019; Fee Paid Rs. 20000/- vide Slip no. 0832347 dated 06.03.2019 endorsed on 07.03.2019

	Pharmacological Group	CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, Glucocorticoids. ATC Code: H02AB06
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Prednisolone 5mg Tablets BP MHRA Approved
	Me-too status	Deltacortril 5mg tablet Reg. No. 000448 M/s Pfizer Pakistan.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility for "Tablet (Steroid)" section.	
456	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (Hormone/General)
	Brand Name + Dosage Form + Strength	REGEN Tablet 1mg
	Composition	Each Film coated tablet contains: Finasteride……..1mg
	Diary No. Date of R & I & fee	Dy. No. 14362 dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829862
	Pharmacological Group	Testosterone-5-alpha reductase inhibitor ATC Code: G04CB01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Finsteride1mg Film-Coated tablet. MHRA Approved
	Me-too status	Finarid-M Tablet Reg. No. 078402 M/s Shaheen Pharmaceuticals
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
457	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	Andro Tablet 150mg
	Composition	Each Film coated tablet contains: Ibandronate Sodium Monohydrate eq. to Ibandronic acid……150mg
	Diary No. Date of R & I & fee	Dy. No. 14352; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No.0829852 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Bisphosphonate agent ATC Code: M05BA06
	Type of Form	Form 5
	Finished product Specification	Aries' specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Ibandronic Acid 150mg Film-coated Tablets MHRA Approved
	Me-too status	Bonheal tablets 150mg Reg. No. 069250 M/s Novamed Pharmaceuticals Lahore.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
458	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	MESTANE Tablet 25mg
	Composition	Each Film coated tablet contains: Exemestane……25mg
	Diary No. Date of R & I & fee	Dy. No. 14399; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No.0829901 dated 06.03.2019 endorsed on 07.03.2019.
	Pharmacological Group	Aromatase inhibitors. ATC Code: L02BG06
	Type of Form	Form 5
	Finished product Specification	Aries' specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exemestane 25 mg film-coated tablets MHRA Approved.
	Me-too status	Aromasin Tablet 25mg Reg. No. 028359 M/s Pfizer Pakistan.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. **Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.**	
459	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	IBUDEX Tablet 400mg
	Composition	Each Film Coated Tablet Contains; Dexibuprofen…….. 400mg
	Diary No. Date of R & I & fee	Dy. No. 14396; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0832342 dated 05.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Propionic acid derivatives ATC Code: M01AE14
	Type of Form	Form 5
	Finished product Specification	Aries' Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 400 mg Film-coated Tablets MHRA Approved.

	Me-too status	Tercica 400mg Tablet Reg. No. 058446 M/s Sami Pharmaceuticals Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
460	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	BESART Tablet 150mg
	Composition	Each Film Coated Tablet contains; Irbesartan USP……..150mg
	Diary No. Date of R & I & fee	Dy. No. 14368; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829868 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code: C09CA04
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan 75 mg, 150 mg and 300 mg film-coated Tablets. MHRA Approved.
	Me-too status	Irecon Tablet 150mg Reg. No. 039726 M/s Barrett Hodgson Pakistan Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
461	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	BESART Tablet 300mg
	Composition	Each Film Coated Tablet contains; Irbesartan USP……..300mg
	Diary No. Date of R & I & fee	Dy. No. 14369; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829869 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain ATC Code: C09CA04
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Irbesartan 75 mg, 150 mg and 300 mg film-coated Tablets. MHRA Approved.
	Me-too status	Irecon Tablet 300mg Reg. No. 039727 M/s Barrett Hodgson Pakistan Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	

	Decision: Approved.	
462	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (Hormone)
	Brand Name + Dosage Form + Strength	ESTRA Tablet 2.0mg
	Composition	Each Tablet Contains; Estradiol Valerate……..2.0mg
	Diary No. Date of R & I & fee	Dy. No. 14363; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829863 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Natural and semisynthetic estrogens, plain. ATC Code: G03CA03
	Type of Form	Form 5
	Finished product Specification	Aries' Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PROGYNOVA 2 mg, coated tablet. ANSM France Approved.
	Me-too status	Progynova Tablet Reg. No. 017864 M/s Bayer Pak (Pvt) Ltd Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	The RRA product is a coated tablet, applied product is uncoated. Justification or correction is required along with submission of requisite fee.
	Decision: Approved with Inovator's specifications as per following label claim: **"Each film coated tablet Contains;** **Estradiol Valerate…….2.0mg"** **Registration letter shall be issued after submission of correct formulation, label and fee of Rs. 7500/- for revision from uncoated tablet to film coated tablet.**	
463	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	BAMRAL Tablet 10mg
	Composition	Each Tablet Contains; Bambuterol HCl……..10mg
	Diary No. Date of R & I & fee	Dy. No. 14366; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829866 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists. ATC Code: R03CC12
	Type of Form	Form 5
	Finished product Specification	Aries' Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BAMBEC® 10 mg Tablets MHRA Approved.
	Me-too status	Bambec Tablet 10mg Reg. No. 017321 M/s Barret Hodgson Pakistan (Pvt)(Ltd) Karachi
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Inovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

464	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	PROX CR Tablet 12.5mg
	Composition	Each Enteric Coated Controlled Release Tablet Contains; Paroxetine HCl USP eq. to Paroxetine …12.5mg
	Diary No. Date of R & I & fee	Dy. No. 14355; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829855 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Selective serotonin reuptake inhibitors. ATC Code: N06AB05
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR 12.5mg, 25mg, 37.5mg USFDA Approved.
	Me-too status	Pariz Tablets 12.5mg Reg. No. 052593 M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
465	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (General)
	Brand Name + Dosage Form + Strength	CO-BESART Tablet 150mg/12.5mg
	Composition	Each Film Coated Tablet Contains; Irbesartan USP……..150mg Hydrochlorothiazide USP….12.5mg
	Diary No. Date of R & I & fee	Dy. No. 14381; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829893 dated 06.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics. C09DA04
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AVALIDE® (irbesartan and hydrochlorothiazide) 150/12.5 mg and 300/12.5 mg film-coated Tablets USFDA Approved.
	Me-too status	Irecon-H Tablet Reg. No. 042272 M/s Barrett Hodgson Pakistan (Pvt) Ltd Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
466	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (Hormone)
	Brand Name + Dosage Form + Strength	NOPROST Vaginal tablet 3mg

	Composition	Each Tablet Contains; Dinoprostone USP …….. 3.0mg
	Diary No. Date of R & I & fee	Dy. No. 14408; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0832350 dated 06.03.2019 endorsed on 07.03.2019.
	Pharmacological Group	UTEROTONICS, Prostaglandins. ATC code: G02AD02
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Ditone E2 Vaginal Tablet Reg. No. 084376 M/s Shaigan Pharmaceutical Rawalpindi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	The RRA reference could not be verified. Evidence of applied product in RRA is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
467	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Oral Liquid Section (General)
	Brand Name + Dosage Form + Strength	AVERON Syrup 4.0mg
	Composition	Each 5ml Contains; Ondansetron Hydrochloride dehydrate eq. to Ondansetron ….4.0mg
	Diary No. Date of R & I & fee	Dy. No. 14360; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829861 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRANEQ 4MG BASE/5MLSOLUTION; ORAL USFDA Approved.
	Me-too status	Dantron Oral Solution Reg. No. 077076 M/s Shrooq Pharmaceuiticals (Pvt) Ltd Lahore.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
468	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Liquid Ampoule Injection Section (General)
	Brand Name + Dosage Form + Strength	RANITIN INJECTION 50mg/2ml
	Composition	Each 2ml Ampoule Contains; Ranitidine HCl eq. Ranitidine … 50mg
	Diary No. Date of R & I & fee	Dy. No. 14375; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829878 dated 04.03.2019 endorsed on 06.03.2019.

	Pharmacological Group	H2-receptor antagonists. ATC Code: A02BA02
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ranitidine 50 mg/2 ml Solution for injection or infusion MHRA Approved.
	Me-too status	Ranulcid Injection Reg. No. 025487 M/s martin Dow Marker
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	The Registration Board in its 294th meeting had decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products.	
469	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Liquid Ampoule Injection Section (General)
	Brand Name + Dosage Form + Strength	FUMIDE INJECTION 20mg/2ml (IV/IM)
	Composition	Each 2ml Ampoule Contains; Furosemide USP……20mg
	Diary No. Date of R & I & fee	Dy. No. 14383; dated 07-03-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829895 dated 06.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	HIGH-CEILING DIURETICS, Sulfonamides, plain. ATC Code: C03CA01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Furosemide 20mg/2ml Solution for Injection. MHRA Approved
	Me-too status	Lasix Injection 20mg Reg. No. 000230 M/s Sanofi-Aventis Pakistan Ltd. Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
470	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Liquid Ampoule Injection Section (General)
	Brand Name + Dosage Form + Strength	CARDIN INJECTION 0.5mg/2ml (IV)
	Composition	Each 2ml Ampoule Contains; Digoxin USP .0.5mg
	Diary No. Date of R & I & fee	Dy. No. 14384; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829896 dated 06.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Digitalis glycosides ATC Code: C01AA05
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Digoxin 250 micrograms/ml Solution for Injection MHRA Approved.
	Me-too status	Lanoxin Injection 2 ml Reg. No. 001608 M/s Getz Pharma (Pvt) Ltd Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
471	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Liquid Ampoule Injection Section (General)
	Brand Name + Dosage Form + Strength	BUVAC Injection 5mg/1ml
	Composition	Each 1ml Ampoule Contains; Bupivacaine HCl USP…….5mg
	Diary No. Date of R & I & fee	Dy. No. 14376; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829879 dated 04.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	ANESTHETICS, LOCAL, Amides ATC Code: N01BB01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed for 1ml Ampoule
	Me-too status	Bucane 5mg/ml Injection Reg. No. 045495 M/s Ophth-Pharma (Pvt) Ltd. Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	Evidence of product in RRA provided is discontinued. Proper Evidence in RRA is required for Bupivacaine HCl 5mg/1ml in 1ml ampoule.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
472	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Liquid Ampoule Injection Section (General)
	Brand Name + Dosage Form + Strength	DROTIC INJECTION 40mg/2ml
	Composition	Each 2ml Ampoule Contains; Drotaverine HCl…40mg
	Diary No. Date of R & I & fee	Dy. No. 14378; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829890 dated 06.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, Papaverine and derivatives. ATC Code: A03AD02
	Type of Form	Form 5
	Finished product Specification	Aries' Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Three European countries Bulgaria, Latvia, Hungary.
	Me-too status	I-Spa 40mg/2ml Injection Reg. No. 097722 M/s Iqra Pharmaceuticals Islamabad.

	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Inovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
473	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Liquid Ampoule Injection Section (General)
	Brand Name + Dosage Form + Strength	NARLOX INJECTION 0.4mg/1ml(IV/IM/SC)
	Composition	Each 1ml Ampoule Contains; Naloxone HCl….0.4mg
	Diary No. Date of R & I & fee	Dy. No. 14386; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0829898 dated 06.03.2019 endorsed on 06.03.2019.
	Pharmacological Group	Antidotes ATC Code: V03AB15
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Naloxone Hydrochloride 400mcg/ml Solution for injection MHRA Approved.
	Me-too status	NXN 0.4mg/ml Injection Reg. No. 107312 M/s Rotex Pharma Islamabad.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
474	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Liquid Ampoule Injection Section (General)
	Brand Name + Dosage Form + Strength	EPIVON INJECTION 500mg/5ml (IV)
	Composition	Each 5ml Ampoule Contains; Valproate Sodium Eq. to Valproic Acid USP ..500mg
	Diary No. Date of R & I & fee	Dy. No. 14407; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0832349 dated 06.03.2019 endorsed on 07.03.2019.
	Pharmacological Group	ANTIEPILEPTICS, Fatty acid derivatives, ATC Code: N03AG01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be verified for applied product.
	Me-too status	Epival IV Injection Reg. No. 023349 M/s Abbott Laboratories Karachi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.
	Remarks of the Evaluator	The Evidence of RRA provided (Depacon USFDA) is discontinued. Evidence of product in other RRA is observed to be of 3ml, 4ml and 10ml. Justification, or revision along with requisite fee is required (Full Fee).
	Decision: Approved as same strength in same volume is approved by USFDA in vial form.	

475	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Oral Liquid Section (General)
	Brand Name + Dosage Form + Strength	Ulcef-1 Suspension 1gm/5ml
	Composition	Each 5ml contains: Sucralfate USP …… 1g
	Diary No. Date of R & I & fee	Dy. No. 13307 dated 07-03-2019. Fee paid Rs. 20000/-
	Pharmacological Group	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD), ATC Code:A02BX02
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml, 90ml, 120ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Antepsin 1g/5ml oral suspension MHRA Approved.
	Me-too status	Acenil Suspension 1gm Reg. No. 069033 M/s Medisave Pharmaceuticals Lahore.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required. iii. Finished product specifications are claimed to be USP Specifications. USP Monograph of the product is required. **The firm was communicated deficiencies and firm has stated that USP specs are a clerical mistake and these should be changed to Innovator's Specs. The firm has not submitted the requisite fee.**
	Decision: Approved with Innovator' s specifications. Registration letter shall be issued after submission of Latest GMP inspection report conducted within last three years along with fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
476	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Ulcef-1 Tablet 1gm
	Composition	Each Film Coated Tablet Contains: Sucralfate USP……1g
	Diary No. Date of R & I & fee	Dy. No. 13306 dated 07-03-2019. Fee paid Rs. 20000/-
	Pharmacological Group	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD), ATC Code:A02BX02
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Sucralfate Tablets USP 1gram USFDA Approved.
	Me-too status	Sucrafate Tablet Reg. No. 010290 M/s Abbott Laboratories Karachi.

	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
477	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (Psychotropic)
	Brand Name + Dosage Form + Strength	Zepra-0.25 Tablets 0.25mg
	Composition	Each Tablet Contains: Alprazolam USP ……..0.25mg
	Diary No. Date of R & I & fee	Dy. No. 13308; dated 07-03-2019; Fee Paid Rs. 20000/-
	Pharmacological Group	ANXIOLYTICS,Benzodiazepine derivatives. ATC Code: 05BA12
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	3×10's
	Approval status of product in Reference Regulatory Authorities	Xanax 250 microgram Tablets MHRA Approved.
	Me-too status	Xanax 0.25mg Tablet Reg. No. 014417 M/s Pfizer Pakistan Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility of "Tablet (psychotropic) section".	
478	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (Psychotropic)
	Brand Name + Dosage Form + Strength	Zepra-0.5 Tablets 0.5mg
	Composition	Each Tablet Contains: Alprazolam USP……..0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13309 dated 07-03-2019. Fee paid Rs. 20000/-
	Pharmacological Group	ANXIOLYTICS,Benzodiazepine derivatives. ATC Code: 05BA12
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	3×10's
	Approval status of product in Reference Regulatory Authorities	Xanax 500 microgram Tablets MHRA Approved.
	Me-too status	Xanax 0.5mg Tablet Reg. No. 012303 M/s Pfizer Pakistan Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility for "psychotropic" products.	

479	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (Psychotropic)
	Brand Name + Dosage Form + Strength	Zepra-1 Tablets 1 mg
	Composition	Each Tablet Contains: Alprazolam……..1mg
	Diary No. Date of R & I & fee	Dy. No. 13310dated 07-03-2019; Fee Paid Rs. 20000/-
	Pharmacological Group	ANXIOLYTICS,Benzodiazepine derivatives. ATC Code: 05BA12
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	3×10's
	Approval status of product in Reference Regulatory Authorities	XANAX (alprazolam)Tablets: 0.25 mg, 0.5 mg, 1 mg, and 2 mg USFDA Approved.
	Me-too status	Xanax 1mg Tablet Reg. No. 013349 M/s Pfizer Pakistan Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility for "psychotropic" products.	
480	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	ALZI 10mg tablet
	Composition	Each film coated tablet contains: Memantine HCl……10mg
	Diary No. Date of R & I & fee	Dy No. 13296 dated 07-03-2019; Fee Paid 20000/-
	Pharmacological Group	Other anti-dementia drugs ATC Code: N06DX01
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Memamentine Hydrochloride 10mg and 20 mg Film-Coated tablets MHRA Approved.
	Me-too status	Afdol 10mg Tablets Reg. No. 044429 M/s AGP Pvt, Ltd. Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
481	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	ALZI 20mg tablet

	Composition	Each film coated tablet contains: Memantine HCl……20mg
	Diary No. Date of R & I & fee	Dy No. 13297 dated 07-03-2019; Fee Paid 20000/-
	Pharmacological Group	Other anti-dementia drugs ATC Code: N06DX01
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Memamentine Hydrochloride 10mg and 20 mg Film-Coated tablets MHRA Approved.
	Me-too status	Memxio 20mg Tablets Reg. No. 110930 M/s AGP Pvt, Ltd. Karachi.
	GMP status	Inspection report dated 22.02.2019 is submitted.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
482	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Denzi-4 tablet 4mg
	Composition	Each film coated tablet contains: Ondansetron (as HCl dehydrate) BP……..4mg
	Diary No. Date of R & I & fee	Dy. No. 13303 dated 07-03-2019. Fee paid 20000/-
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	1×10's
	Approval status of product in Reference Regulatory Authorities	Ondansetron 4 mg & 8 mg (Ondansetron Hydrochloride dehydrate) MHRA Approved.
	Me-too status	Zofran Tablets 4 mg Reg. No. 020667 M/s GSK Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
483	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Denzi-8 tablet 8mg
	Composition	Each film coated tablet contains: Ondansetron as HCl dehydrate BP……..8mg
	Diary No. Date of R & I & fee	Dy. No. 13302 dated 07-03-2019. Fee Paid Rs. 20000/-

	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	1×10's
	Approval status of product in Reference Regulatory Authorities	Ondansetron 4 mg & 8 mg (Ondansetron Hydrochloride dehydrate) MHRA Approved.
	Me-too status	Zofran Tablets 8 mg Reg. No. 020668 M/s GSK Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
484	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Lora-5 tablet 5mg
	Composition	Each film coated tablet contains: Desloratadine…….5mg
	Diary No. Date of R & I & fee	Dy. No. 13298; 07-03-2019; 20000/-
	Pharmacological Group	Other antihistamines for systemic use. ATC Code: R06AX27
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	10's, as per SRO
	Approval status of product in Reference Regulatory Authorities	Desloratadine 5mg Film-Coated Tablets MHRA Approved
	Me-too status	Alenor Reditab 5mg Tablet Reg. No. 067054 M/s Macter International (Pvt.) Ltd.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
485	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (psychotropic)
	Brand Name + Dosage Form + Strength	Zepam-0.5 tablets 0.5mg
	Composition	Each tablet contains: Clonazepam BP……..0.5mg
	Diary No. Date of R & I & fee	Dy. No. 13311 dated 07-03-2019. Fee paid Rs. 20000/-
	Pharmacological Group	ANTIEPILEPTICS, Benzodiazepine derivatives. ATC Code: N03AE01
	Type of Form	Form 5
	Finished product Specification	USP Specifications.

	Pack size & Demanded Price	3×10's
	Approval status of product in Reference Regulatory Authorities	Clonazepam Neuraxpharm 0.5mg, 1mg and 2 mg Tablets MHRA Approved.
	Me-too status	RIVOTRIL TABLET 0.5mg Reg. No. 001049 M/s Martin Dow Ltd., Plot No. 37 Sector 19 Korangi Industrial Area Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility for "psychotropic" products.	
486	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (psychotropic)
	Brand Name + Dosage Form + Strength	Zepam-1 tablet 1mg
	Composition	Each tablet contains: Clonazepam BP……1mg
	Diary No. Date of R & I & fee	Dy. No.13312 dated 07-03-2019. Fee paid Rs. 20000/-
	Pharmacological Group	ANTIEPILEPTICS, Benzodiazepine derivatives. ATC Code: N03AE01
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	3×10's
	Approval status of product in Reference Regulatory Authorities	Clonazepam Neuraxpharm 0.5mg, 1mg and 2 mg Tablets MHRA Approved.
	Me-too status	Curo 1mg Tablet Reg. No. 065700 M/s Wilshire Laboratories Lahore.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility for "psychotropic" products.	
487	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (psychotropic)
	Brand Name + Dosage Form + Strength	Zepam-2 tablet 2mg
	Composition	Each tablet contains: Clonazepam…….2mg
	Diary No. Date of R & I & fee	Dy. No. 13313 dated 07-03-2019; Fee Paid Rs. 20000/-
	Pharmacological Group	ANTIEPILEPTICS, Benzodiazepine derivatives. ATC Code: N03AE01
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	3×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Clonazepam Neuraxpharm 0.5mg, 1mg and 2 mg Tablets MHRA Approved.
	Me-too status	RIVOTRIL TABLET 2mg Reg. No. 003626 M/s Martin Dow Ltd., Plot No. 37 Sector 19 Korangi Industrial Area Karachi.

	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility for "psychotropic" products.	
488	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Monti-10 tablet 10mg
	Composition	Each Film Coated Tablet contains: Montelukast(as sodium salt) BP…….10mg
	Diary No. Date of R & I & fee	Dy. No. 13299 dated 07-03-2019 Fee Paid 20000/-
	Pharmacological Group	Leukotriene receptor antagonists. ATC Code: R03DC03
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	1×14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Montelukast 10mg Film-Coated Tablets MHRA approved.
	Me-too status	Singulair 10mg Tablet Reg. No. 025259 M/s.OBS Healthcare (Pvt) Ltd Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
489	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Monti-4 Chewable tablet 4mg
	Composition	Each chewable tablet contains: Montelukast(as sodium salt) BP…….4mg
	Diary No. Date of R & I & fee	Dy. No. 13300 dated 07-03-2019 Fee Paid 20000/-
	Pharmacological Group	Leukotriene receptor antagonists. ATC Code: R03DC03
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	1×14's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Montelukast 4mg Chewable Tablets MHRA approved.
	Me-too status	Montelex 4mg Chewable Tablet Reg. 054328 M/s Caylex Pharmceuticals Lahore..
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	

490	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Monti-5 Chewable tablet 5mg
	Composition	Each chewable tablet contains: Montelukast(as sodium salt) BP…….5mg
	Diary No. Date of R & I & fee	Dy. No. 13301 dated 07-03-2019 Fee Paid 20000/-
	Pharmacological Group	Leukotriene receptor antagonists. ATC Code: R03DC03
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	1×14's, AS per SRO
	Approval status of product in Reference Regulatory Authorities	Montelukast 5mg Chewable Tablets MHRA approved.
	Me-too status	Montaza Chewable Tab 5mg Reg. 048754 M/s Zafa Pharmaceutical Lab Karachi.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
491	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Tablet Section (General)
	Brand Name + Dosage Form + Strength	Gasto-50 tablet 50mg
	Composition	Each film coated tablet contains: Itopride hydrochloride…….50mg
	Diary No. Date of R & I & fee	Dy. No. 13314 dated 07-03-2019. Fee paid Rs. 20000/-
	Pharmacological Group	Propulsives ATC Code: A03FA07
	Type of Form	Form 5
	Finished product Specification	Akson's Specifications.
	Pack size & Demanded Price	10's, 20's, 30's, AS per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton Tablets 50mg (Film Coated) PMDA Japan Approved.
	Me-too status	Inviton 50mg Tablets Reg. No. 096543 M/s Invictus Pharma Rawat.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
492	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486) Injectable Ampoule and Infusion Section (General)
	Brand Name + Dosage Form + Strength	Denzi-4 Injection 4mg/2ml
	Composition	Each 2ml Ampoule contains:

		Ondansetron as HCl dehydrate BP……..4mg
	Diary No. Date of R & I & fee	Dy. No. 13305 dated 07-03-2019. Fee Paid 20000/-
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	4ml, as per SRO.
	Approval status of product in Reference Regulatory Authorities	Ondansetron 2mg/ml Solution for Injection/Infusion - UK/H/3802/001/DC; PL 00057/0915 MHRA Approved.
	Me-too status	Welstro Injection 4mg/2ml Reg. No. 075397 M/s Welwink Gujranwala.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	
493.	Name and address of manufacturer/ Applicant	M/s Akson Pharmaceuticals (pvt.) Ltd. Plot no. 9-B/1&2, Sector D-1, Old industrial Estate, Mirpur, Azad Kashmir. (DML No. 000486)
	Brand Name + Dosage Form + Strength	Denzi-8 Injection 8mg/4ml
	Composition	Each 4ml Ampoule contains: Ondansetron as HCl dehydrate BP……..8mg
	Diary No. Date of R & I & fee	Dy. No. 13304 dated 07-03-2019. Fee Paid 20000/-
	Pharmacological Group	ANTIEMETICS AND ANTINAUSEANTS, Serotonin (5HT3) antagonists. ATC Code: A04AA01
	Type of Form	Form 5
	Finished product Specification	BP Specifications.
	Pack size & Demanded Price	4ml, as per SRO.
	Approval status of product in Reference Regulatory Authorities	Ondansetron 4mg/2ml Injection (4ml Ampoules) MHRA Approved.
	Me-too status	Ondansetron 8mg/4mlInjection Reg. No. 110920 M/s Bajwa Pharmaceuticals Sheikhupura.
	GMP status	Last inspection conducted on 22.02.2019.
	Remarks of the Evaluator	i. Copy of section approval letter is required. ii. Copy of latest GMP inspection report/certificate is required.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP certificate/ inspection report conducted within last 3 years by QA&LT Division.	

Item No. XV: Agenda of Evaluator PEC-XVII.

Export Facilitation cases:

The following applications were received vide letter No.F.1-6/2019-PR-I (EFD) dated 06th October, 2022 from Assistant Director (PR-I/EFD), PE & R, Division for evaluation on priority basis in pursuance of decision in 133rd meeting of DRAP Authority held on 13th April 2022, regarding export facilitation (Grant of registration

on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year).

Case No. 1: Registration Applications requiring submission of stability data:

494.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	JARDY-MET XR 5mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…….5mg Metformin HCl extended release…….1000mg
	Diary No. Date of R& I & fee	Dy. No. 6520 dated 14-02-2019, Fee Rs: 50,000/- dated 23-11-2018 vide deposit slip No.0809686.
	Pharmacological Group	Antidiabetic (Sodium/glucose co transporter 2 (SGLT2) inhibitor and biguanide class)
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, (4×7's); As per SRO
	Approval status of product in Reference Regulator Authorities	Synjardy XR 5/1000mg film coated tablets (USFDA Approved)
	Me-too status	NA
	GMP status	DML renewal inspection conducted on 21-10-2020, wherein panel recommends the renewal of Drug Manufacturing License to M/s CCL Pharmaceuticals (Pvt) Ltd., by way of formulation to the following sections only Liquid Injectable Section (General) Tablet Section (General) Capsule Section (General) Dry powder suspension Capsule Section (Steroid) Oral liquid section
	Remarks of the Evaluator (PEC-XVII)	Tablet (General) Section (Revised) approval granted vide Licensing Division, letter No.F.1-8/84-Lic (Vol-III) dated 22-06-2018.

STABILITY STUDY DATA	
Manufacturer of API	(Empagliflozin) M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. (Metformin hydrochloride) M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.
API Lot No.	Empagliflozin: L-E-20200409-D01-E06-01) Metformin Hydrochloride: MT01130220l
Description of Pack (Container closure system)	Alu-Alu blister packed in uni carton
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JMXA-T2-20	JMXA-T3-20	JMXA-T4-20
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	31-08-2020	31-08-2020	31-08-2020
No. of Batches	03		
Date of Submission	09-06-2021 (16007)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 297th meeting dated 12-15th January, 2021, decided to approve registration of Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg. Inspection date: 14-10-2020. The report shows that: • Finished Pharmaceutical Product stability testing was conducted on HPLC R&D # 19 for Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg which were not 21 CFR compliant for initial 6 months. • Finished Pharmaceutical Product stability studies conducted from 9 months onward was on 21 CFR compliant. HPLC. Q.C .NO 122. • Adequate monitoring and control were available for stability chamber.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	1. Copies of COAs (Batch#L-E-20200409-D01-E06-01) of API (Empagliflozin) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore are submitted. 2. Copies of COAs (Batch#MT01130220) of API (Metformin hydrochloride) from M/s Wanbury limited, Andra Pradesh India and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Empagliflozin: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively.

		Batches:(20160606,20161017,20161219) 10 days stress stability study at conditions 60°C ± 2°C, Photolysis 4500 ± 500LX and 92.5%± 5%RH at 0, 5th & 10th days intervals also provided. Metformin hydrochloride: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 60 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(MET-E-06640908, MET-E-06650908, MET-E-06660908)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Empagliflozin: Firm has submitted copy of GMP certificate dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China issued by Liaoning Fuxin Management committee, Fluoride Industrial Development Zone. Valid till 23-08-2023. For Metformin hydrochloride: The firm has submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 06-02-2019 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	For Empagliflozin: The firm has submitted copy of invoice No. HN20060302-H dated 03-06-2020 from exporter M/s Beijing Sino Hanson Import & Export Col, Ltd. No.3, Zhonghe road, Fengtai District, Beijing China, for import of 10kgs of Empagliflozin (Batch No. L-E-20200409-D01-E06-01) in name of M/s CCL Pharmaceuticals Private Ltd. Lahore attested by AD (I&E) DRAP Lahore dated 18-06-2020. For Metformin hydrochloride: The firm has submitted copy of invoice No. 92003089 dated 29-02-2020 from Wanbury Limited, BSEL Techpark, 'B' Wing, 10th Floor, Sector 30-A, Opp. Vashi Railway Station, Vashi, Navi Mumbai – 400703, India for import of 8000kgs Metformin HCl (1280Kgs,Batch No. MT01130220 used in instant trial batches) in the name of CCL Pharmaceuticals, Lahore attested by AD (I & E) DRAP, Lahore dated 05-03-2020.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Drug excipients compatibility study performed.

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>JMXA-T2-20</td><td>1000 tablets</td><td>08-2020</td></tr><tr><td>JMXA-T3-20</td><td>1000 tablets</td><td>08-2020</td></tr><tr><td>JMXA-T4-20</td><td>1000 tablets</td><td>08-2020</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Synjardy XR tablet (5/1000mg) Batch No. 3183238 & Synjardy XR tablet (25/1000mg), Batch No. 3167491 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
</table>

REMARKS OF EVALUATOR (PEC-XVII)

Deficiency/Observation	**Response by Pharma.**
Submit valid GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.	The firm submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 08-02-2022 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.
In finished drug product testing method, standard and sample absorbance are mentioned in the formula. However, dissolution and content uniformity tests are being performed on HPLC. Clarify or else revise finished drug product testing method as per employed testing methods.	The firm re-submit finished drug product analytical method with revised analysis formula. The firm further stated that since it is a typographical error and not a variation, fee is not applicable as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
Submit CoA of working standard	Firm submitted CoA of working standard.

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

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

495.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	JARDY-MET XR 10mg/1000mg Tablet

	Composition	Each Film Coated Tablet Contains: Empagliflozin…….10mg Metformin HCl extended release…….1000mg
	Diary No. Date of R& I & fee	Dy. No.6521 dated 14-02-2019, Fee Rs: 50,000/- dated 23-11-2018 vide deposit slip No.0809687
	Pharmacological Group	Antidiabetic (Sodium/glucose co transporter 2 (SGLT2) inhibitor and biguanide class)
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, (4×7's); As per SRO
	Approval status of product in Reference Regulator Authorities	Synjardy XR 10/1000mg film coated tablets (USFDA Approved)
	Me-too status	NA
	GMP status	DML renewal inspection conducted on 21-10-2020, wherein panel recommends the renewal of Drug Manufacturing License to M/s CCL Pharmaceuticals (Pvt) Ltd., by way of formulation to the following sections only Liquid Injectable Section (General) Tablet Section (General) Capsule Section (General) Dry powder suspension Capsule Section (Steroid) Oral liquid section
	Remarks of the Evaluator	Tablet (General) Section (Revised) approval granted vide Licensing Division, letter No.F.1-8/84-Lic (Vol-III) dated 22-06-2018.

STABILITY STUDY DATA

Manufacturer of API	(Empagliflozin) M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. (Metformin hydrochloride) M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.		
API Lot No.	Empagliflozin: L-E-20200409-D01-E06-01) Metformin Hydrochloride: MT01130220		
Description of Pack (Container closure system)	Alu-Alu blister packed in uni carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JMXB-T2-20	JMXB-T3-20	JMXB-T4-20
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	31-08-2020	31-08-2020	12-08-2020
No. of Batches	03		
Date of Submission	09-06-2021 (16005)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 297th meeting dated 12-15th January, 2021, decided to approve registration of Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg. Inspection date: 14-10-2020. The report shows that: • Finished Pharmaceutical Product stability testing was conducted on HPLC R&D # 19 for Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg which were not 21 CFR compliant for initial 6 months. • Finished Pharmaceutical Product stability studies conducted from 9 months to onward was on 21 CFR compliant. HPLC. Q.C .NO 122 Adequate monitoring and control were available for stability chamber. The report shows that: • The HPLC software is 21 CFR compliant as per record available with the firm. • Audit Trail on the testing reports on Tenofovir Alafenamide Fumarate API and Vireof-N tablets 25mg is available. • The firm has adequate monitoring and control system for stability chambers.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	1. Copy of COA (Batch#L-E-20200409-D01-E06-01) of API (Empagliflozin) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore is submitted. 2. Copy of COA (Batch#MT01130220) of API (Metformin hydrochloride) from M/s Wanbury limited, Andra Pradesh India and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Empagliflozin: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively. Batches:(20160606,20161017,20161219) 10 days stress stability study at conditions 60°C ± 2°C, Photolysis 4500 ± 500LX and 92.5%±

		5%RH at 0, 5th & 10th days intervals also provided. Metformin hydrochloride: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 60 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(MET-E-06640908, MET-E-06650908, MET-E-06660908)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Empagliflozin: Firm has submitted copy of GMP certificate dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China issued by Liaoning Fuxin Management committee, Fluoride Industrial Development Zone. Valid till 23-08-2023. For Metformin hydrochloride: The firm has submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 06-02-2019 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	For Empagliflozin: The firm has submitted copy of invoice No. HN20060302-H dated 03-06-2020 from exporter M/s Beijing Sino Hanson Import & Export Col, Ltd. No.3, Zhonghe road, Fengtai District, Beijing China, for import of 10kgs of Empagliflozin (Batch No. L-E-20200409-D01-E06-01) in name of M/s CCL Pharmaceuticals Private Ltd. Lahore attested by AD (I&E) DRAP Lahore dated 18-06-2020. For Metformin hydrochloride: The firm has submitted copy of invoice No. 92003089 dated 29-02-2020 from Wanbury Limited, BSEL Techpark, 'B' Wing, 10th Floor, Sector 30-A, Opp. Vashi Railway Station, Vashi, Navi Mumbai – 400703, India for import of 8000kgs Metformin HCl (1280Kgs, Batch No. MT01130220 used in instant trial batches) in the name of CCL Pharmaceuticals, Lahore attested by AD (I & E) DRAP, Lahore dated 05-03-2020.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (where applicable)	Drug excipients compatibility study performed.

10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** JMXB-T2-20 / 1000 tablets / 08-2020 JMXB-T3-20 / 1000 tablets / 08-2020 JMXB-T4-20 / 1000 tablets / 08-2020
11.	Record of comparative dissolution data (where applicable)	Provided Comparative dissolution was performed against Synjardy XR tablet (5/1000mg) Batch No. 3183217 & Synjardy XR tablet (25/1000mg), Batch No. 3167491 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator (PEC-XVII)

Deficiency/Observation	**Response by Pharma.**
Submit valid GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.	The firm submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 08-02-2022 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.
In finished drug product testing method, standard and sample absorbance are mentioned in the formula. However, dissolution and content uniformity tests are being performed on HPLC. Clarify or else revise finished drug product testing method as per employed testing methods.	The firm re-submit finished drug product analytical method with revised analysis formula. The firm further stated that since it is a typographical error and not a variation, fee is not applicable as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
Submit CoA of working standard	Firm submitted CoA of working standard.

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

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

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

496.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	JARDY-MET XR 12.5mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…….12.5mg

		Metformin HCl extended release…….1000mg
	Diary No. Date of R& I & fee	Dy. No.6522 dated 14-02-2019 , Fee Rs: 50,000/- dated 23-11-2018 vide deposit slip No.0809688
	Pharmacological Group	Antidiabetic (Sodium/glucose co transporter 2 (SGLT2) inhibitor and biguanide class)
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, (4×7's); As per SRO
	Approval status of product in Reference Regulator Authorities	Synjardy XR 12.5/1000mg film coated tablets (USFDA Approved)
	Me-too status	NA
	GMP status	DML renewal inspection conducted on 21-10-2020, wherein panel recommends the renewal of Drug Manufacturing License to M/s CCL Pharmaceuticals (Pvt) Ltd., by way of formulation to the following sections only Liquid Injectable Section (General) Tablet Section (General) Capsule Section (General) Dry powder suspension Capsule Section (Steroid) Oral liquid section
	Remarks of the Evaluator	Tablet (General) Section (Revised) approval granted vide Licensing Division, letter No.F.1-8/84-Lic (Vol-III) dated 22-06-2018.

STABILITY STUDY DATA

Manufacturer of API	(Empagliflozin) M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. (Metformin hydrochloride) M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.		
API Lot No.	Empagliflozin: L-E-20200409-D01-E06-01) Metformin Hydrochloride: MT01130220		
Description of Pack (Container closure system)	Alu-Alu blister packed in uni carton		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JMXC-T2-20	JMXC-T3-20	JMXC-T4-20
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	27-09-2020	27-09-2020	27-09-2020
No. of Batches	03		
Date of Submission	09-06-2021 (16004)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 297th meeting dated 12-15th January, 2021, decided to approve registration of Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg. Inspection date: 14-10-2020. The report shows that: • Finished Pharmaceutical Product stability testing was conducted on HPLC R&D # 19 for Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg which were not 21 CFR compliant for initial 6 months. • Finished Pharmaceutical Product stability studies conducted from 9 months to onward was on 21 CFR compliant. HPLC. Q.C .NO 122 • Adequate monitoring and control were available for stability chamber.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	1. Copy of COA (Batch#L-E-20200409-D01-E06-01) of API (Empagliflozin) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore is submitted. 2. Copy of COA (Batch#MT01130220) of API (Metformin hydrochloride) from M/s Wanbury limited, Andra Pradesh India and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Empagliflozin: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively. Batches:(20160606,20161017,20161219) 10 days stress stability study at conditions 60˚C ± 2˚C, Photolysis 4500 ± 500LX and 92.5%± 5%RH at 0, 5th & 10th days intervals also provided. Metformin hydrochloride: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30˚C ± 2˚C / 65% ± 5%RH for 60 months and at Accelerated conditions; 40˚C ± 2˚C

<table>
<tr><td></td><td></td><td>/ 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively.
Batches:(MET-E-06640908, MET-E-06650908, MET-E-06660908)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td><u>For Empagliflozin:</u> Firm has submitted copy of GMP certificate dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China issued by Liaoning Fuxin Management committee, Fluoride Industrial Development Zone. Valid till 23-08-2023.
<u>For Metformin hydrochloride:</u> The firm has submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 06-02-2019 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td><u>For Empagliflozin</u>: The firm has submitted copy of invoice No. HN20060302-H dated 03-06-2020 from exporter M/s Beijing Sino Hanson Import & Export Col, Ltd. No.3, Zhonghe road, Fengtai District, Beijing China, for import of 10kgs of Empagliflozin (Batch No. L-E-20200409-D01-E06-01) in name of M/s CCL Pharmaceuticals Private Ltd. Lahore attested by AD (I&E) DRAP Lahore dated 18-06-2020.
<u>For Metformin hydrochloride</u>: The firm has submitted copy of invoice No. 92003089 dated 29-02-2020 from Wanbury Limited, BSEL Techpark, 'B' Wing, 10th Floor, Sector 30-A, Opp. Vashi Railway Station, Vashi, Navi Mumbai – 400703, India for import of 8000kgs Metformin HCl (1280Kgs,Batch No. MT01130220 used in instant trial batches) in the name of CCL Pharmaceuticals, Lahore attested by AD (I & E) DRAP, Lahore dated 05-03-2020.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Drug excipients compatibility study performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>JMXC-T2-20</td><td>1000 tablets</td><td>09-2020</td></tr>
<tr><td>JMXC-T3-20</td><td>1000 tablets</td><td>09-2020</td></tr>
<tr><td>JMXC-T4-20</td><td>1000 tablets</td><td>09-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Synjardy XR tablet (12.5/1000mg) Batch No.</td></tr>
</table>

		3183240 & Synjardy XR tablet (25/1000mg), Batch No. 3167491 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator (PEC-XVII)

Deficiency/Observation	**Response by Pharma.**
Submit valid GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.	The firm submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 08-02-2022 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.
In finished drug product testing method, standard and sample absorbance are mentioned in the formula. However, dissolution and content uniformity tests are being performed on HPLC. clarify or else revise finished drug product testing method as per employed testing mthods.	The firm re-submit finished drug product analytical method with revised analysis formula. The firm further stated that since it is a typographical error and not a variation, fee is not applicable as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
Submit COA of working standard.	Firm submitted CoA of working standard.

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

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

497.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	JARDY-MET XR 25mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…….25mg Metformin HCl extended release…….1000mg
	Diary No. Date of R& I & fee	Dy. No.6523 dated 14-02-2019 , Fee Rs: 50,000/- dated 23-11-2018 vide deposit slip No.0809690
	Pharmacological Group	Antidiabetic (Sodium/glucose co transporter 2 (SGLT2) inhibitor and biguanide class)
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, (4×7's); As per SRO

	Approval status of product in Reference Regulator Authorities	Synjardy XR 25/1000mg film coated tablets (USFDA Approved)
	Me-too status	NA
	GMP status	DML renewal inspection conducted on 21-10-2020, wherein panel recommends the renewal of Drug Manufacturing License to M/s CCL Pharmaceuticals (Pvt) Ltd., by way of formulation to the following sections only Liquid Injectable Section (General) Tablet Section (General) Capsule Section (General) Dry powder suspension Capsule Section (Steroid) Oral liquid section
	Remarks of the Evaluator	Tablet (General) Section (Revised) approval granted vide Licensing Division, letter No.F.1-8/84-Lic (Vol-III) dated 22-06-2018.

STABILITY STUDY DATA

Manufacturer of API	(Empagliflozin) M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China. (Metformin hydrochloride) M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.		
API Lot No.	Empagliflozin: L-E-20200409-D01-E06-01) Metformin Hydrochloride: MT01130220		
Description of Pack (Container closure system)	Alu-Alu blister packed in uni carton		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	JMXD-T2-20	JMXD-T3-20	JMXD-T4-20
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	27-09-2020	27-09-2020	27-09-2020
No. of Batches	03		
Date of Submission	09-06-2021 (16006)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection for authenticity of stability data of their products conducted by the panel, on the basis of which Registration Board in its 297th meeting dated 12-15th January, 2021, decided to approve registration of Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg. Inspection date: 14-10-2020.

		The report shows that: • Finished Pharmaceutical Product stability testing was conducted on HPLC R&D # 19 for Brivatam Tablets 10mg, Brivatam Tablets 25mg, Brivatam Tablets 50mg, Brivatam Tablets 75mg and Brivatam Tablets 100mg which were not 21 CFR compliant for initial 6 months. • Finished Pharmaceutical Product stability studies conducted from 9 months to onward was on 21 CFR compliant. HPLC. Q.C .NO 122 • Adequate monitoring and control were available for stability chamber.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	1. Copy of COA (Batch#L-E-20200409-D01-E06-01) of API (Empagliflozin) from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Liaoning Province, China and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore is submitted. 2. Copy of COA (Batch#MT01130220) of API (Metformin hydrochloride) from M/s Wanbury limited, Andra Pradesh India and M/s CCL pharmaceuticals (Pvt) Ltd. Lahore is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Empagliflozin: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24 & 0, 1, 2, 3 & 6 months respectively. Batches:(20160606,20161017,20161219) 10 days stress stability study at conditions 60°C ± 2°C, Photolysis 4500 ± 500LX and 92.5%± 5%RH at 0, 5th & 10th days intervals also provided. Metformin hydrochloride: Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 65% ± 5%RH for 60 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, 60 & 0, 1, 2, 3 & 6 months respectively. Batches:(MET-E-06640908, MET-E-06650908, MET-E-06660908)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	For Empagliflozin: Firm has submitted copy of GMP certificate dated 24-08-2020 in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng Country (Yi Ma Tu), Fuxing City, Liaoning Province, China issued by Liaoning Fuxin Management

<table>
<tr><td></td><td></td><td>committee, Fluoride Industrial Development Zone. Valid till 23-08-2023.
<u>For Metformin hydrochloride:</u> The firm has submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 06-02-2019 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td><u>For Empagliflozin</u>: The firm has submitted copy of invoice No. HN20060302-H dated 03-06-2020 from exporter M/s Beijing Sino Hanson Import & Export Col, Ltd. No.3, Zhonghe road, Fengtai District, Beijing China, for import of 10kgs of Empagliflozin (Batch No. L-E-20200409-D01-E06-01) in name of M/s CCL Pharmaceuticals Private Ltd. Lahore attested by AD (I&E) DRAP Lahore dated 18-06-2020.
<u>For Metformin hydrochloride</u>: The firm has submitted copy of invoice No. 92003089 dated 29-02-2020 from Wanbury Limited, BSEL Techpark, 'B' Wing, 10th Floor, Sector 30-A,
Opp. Vashi Railway Station, Vashi, Navi Mumbai – 400703, India for import of 8000kgs Metformin HCl (1280Kgs,Batch No. MT01130220 used in instant trial batches) in the name of CCL Pharmaceuticals, Lahore attested by AD (I & E) DRAP, Lahore dated 05-03-2020.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Drug excipients compatibility study performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>JMXD-T2-20</td><td>1000 tablets</td><td>09-2020</td></tr>
<tr><td>JMXD-T3-20</td><td>1000 tablets</td><td>09-2020</td></tr>
<tr><td>JMXD-T4-20</td><td>1000 tablets</td><td>09-2020</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Provided
Comparative dissolution was performed against Synjardy XR tablet (25/1000mg), Batch No. 3167491 in HCl buffer (pH 1.2), Acetate buffer (pH 4.5) & Phosphate buffer (pH 6.8)</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
</table>

Remarks of Evaluator (PEC-XVII)

Deficiency/Observation	Response by Pharma.
Submit valid GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India.	The firm submitted copy of GMP certificate of M/s Wanbury limited, Doctors Organic Chemicals Division, K. Illindalaparru – 534217, Iragavaram Manadal, West Godavari District, Andra Pradesh, India issued on dated 08-02-2022 by Drugs Control Administration, Andra Pradesh India valid for three (03) years from the date of issue.
In finished drug product testing methods, standard and sample absorbance are mentioned in the formula, however, in the submitted method, dissolution and content uniformity tests are being performed on HPLC. Revise finished drug product testing method as per method employed/performed.	The firm re-submit finished drug product analytical method with revised analysis formula. The firm further stated that since it is a typographical error and not a variation, fee is not applicable as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
Submit COA of working standard.	Firm submitted CoA of working standard

Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

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

498.	Name and address of manufacturer / Applicant	Applicant: M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore. Manufacturer: M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	COLIST INJECTION 2 million IU Lyophilized Powder for solution for injection/infusion
	Composition	Each vial contains: Colistimethate Sodium……2 million IU
	Diary No. Date of R& I & fee	Dy. No 11107 Dated 05-03-2019, Rs. 50,000/- dated 05-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	COLOMYCIN 2 million International Units (IU) (UK)
	Me-too status	Colistimethate Sodium powder for solution for IV injection/infusion of M/s Mukhtar Enterprises Lahore. Registration No. 094757
	GMP status	DML renewal inspection conducted on 21-10-2020, wherein panel recommends the renewal of Drug Manufacturing License to M/s CCL Pharmaceuticals (Pvt) Ltd., by way of formulation to the following sections only Liquid Injectable Section (General) Tablet Section (General) Capsule Section (General)

		Dry powder suspension Capsule Section (Steroid) Oral liquid section
	Remarks of the Evaluator	Decision of 293rd meeting of Drug Registration Board "Deferred for submission of product development data."

STABILITY STUDY DATA			
Manufacturer of API	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd.		
API Lot No.	CMSG 1902001		
Description of Pack (Container closure system)	Vial (transparent glass vial, 10ml)		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	359DS01	359DS02	359DS03
Batch Size	300 vials	300 vials	300 vials
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	07-2020	07-2020	07-2020
No. of Batches	03		
Date of Submission	08-03-2022 (6366)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to 307th meeting of DRB held from 08th-10th June,2021, wherein the product Esorid 40mg IV injection has been approved (Contract manufacturing) by referring to the inspection report of M/s Nabiqasim Industries, Karachi for their product Esomax injection, presented in 294th meeting of DRB, held on 9-04-2020. The board decided to approve Esomax 40mg & Esvin 40mg injection (Contract manufacturing). However, it is also mentioned that the scope of the inspection report pertains to the "authenticity of formulation" only.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch# CMSG 1902001) of API from M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujina Province, China and M/s Nabiqasim Industries (Pvt.) Ltd. Karachi is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Stability study is conducted at Long Term conditions; 25˚C ± 2˚C / 60% ± 5%RH for 36 months and at Accelerated conditions; 40˚C ± 2˚C

<table>
<tr><td></td><td></td><td>/ 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36 & 0, 1, 2, 3 & 6 months respectively.
Batches:(CMS1707001,CMS1707002, CMS1707003)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of “Written confirmation for active substances exported to EU” dated 22-09-2020 in the name of M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. No.8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, China issued by Fujian, Food & Drug Administration valid till 21-09-2022. It also states that the manufacturing plant complies with the requirements of the Chinese Good Manufacturing practices (= GMP of EU, WHO/ICH Q7). The drug does not have Chinese approval number as it is for export-only.
The firm has also provided copy of Drug Manufacturing License No. (Min) 20160089, of M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. No.8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, China valid till 21-09-2025. Details of API are not mentioned in the DML. (DML verifiable online)</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Firm has submitted copy of invoice No. FXIN1902141D dated 20-03-2019 in the name of M/s Nabiqasim Industries (Pvt) Ltd. Karachi, attested by AD (I & E), DRAP Karachi vide No. 1541/21-05-19 dated 24/05/2019 for the import of 0.6kg Colistimethate sodium Non-sterile USP, having batch No. CMSG1902001 from Livzon Group Fuzhou Fuxing pharmaceutical co., Ltd. China.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies
(Where applicable)</td><td>According to the firm, the formulation has been developed as per reference product Colomycin 2 M IU (Teva limited, UK), the formulation of colistimethate sodium 2 M IU is qualitatively same as per reference product, hence compatibility study not applicable.
The reference product contains no other ingredients except colistimethate sodium.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>359DS01</td><td>300 vials</td><td>07-2020</td></tr>
<tr><td>359DS02</td><td>300 vials</td><td>07-2020</td></tr>
<tr><td>359DS03</td><td>300 vials</td><td>07-2020</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Not applicable</td></tr>
</table>

12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, CoA, summary data sheets etc.	Stability study data for Microbial assay (Bioassay) in the form of inhibition zones measurements provided
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The product specifications of colistimethate sodium injection based on USP and there is no application of HPLC in testing method because the assay method based on microbial assay therefore compliance record of HPLC software 21 CFR and audit trail reports are not applicable
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator (PEC-XVII)

Deficiency/Observation	**Response by Pharma.**
Provide API stability data as per Zone IV-A conditions. Stability data provided at following conditions: Stability study is conducted at Long Term conditions; 25˚C ± 2˚C / 60% ± 5%RH for 36 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months.	Firm submitted Stability studies data as per zone IV-B and stated that it is more stressful than zone IV-A.
Description & solubility specifications of API as provided by the firm, termed as USP. However, these specifications are mentioned as "In-house" by the API manufacturer. Also do not exist in USP official monograph of API.	Description and Solubility test are not present in USP Monograph of Colistemethate Sodium. These are additional tests performed by API Manufacturer in addition to USP Tests.
Microbial contamination test/specifications provided in CoA of API by the firm. However, in analytical testing method of API, the same test not mentioned/provided.	Microbial contamination test is mention in Analytical Test Specification. This test is performed as per <USP 61>. *The firm again provided CoA of API from drug substance manufacturer.*
Provide legible/clear copy of DML of API manufacturer.	Firm submitted legible copy of DML of API manufacturer.
The firm has mentioned in stability studies protocol, the Sterility test but the same is not available in stability studies data.	As per USP Monograph, Sterility test is not required for API testing. According to USP Colistimethate Sodium must be subjected to further processing during the preparation of injectable dosage forms. *Response of the firm has not clarified the query/observation.*
CoA of reference/working standard not provided.	Reference standard CoA will be provided. However, API Manufacturer CoA of lot being used in Developmental studies provided.
Justify use of non-sterile API (as evident from lack of sterility testing in CoA & import invoice of API) in manufacturing of injectable dosage form as labelling requirements of Colistimethate Sodium USP states "Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms. However, as per manufacturing record of trial batches submitted, the sterilization process not mentioned.	As per USP Monograph, when label states that Colistimethate Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for Bacterial endotoxins. As per submitted Manufacturing Record and CoA of FPP, BET is performed according to USP. *However, it is stated that as per manufacturing record of trial batches submitted by the firm, there is no details regarding the "further processing".* *USP monograph for Colistimethate sodium include the following labelling requirements:*

	Labeling—*Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.* ***Other requirements***—*Where the label states that Colistimethate Sodium is sterile; it meets the requirements for Sterility and Bacterial endotoxins under Colistimethate for Injection. Where the label states that Colistimethate Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for Bacterial endotoxins under Colistimethate for Injection.*
• Justify the following: ➢ Dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).	The determined potency is equal to 100.0% in terms of CBA. Hence, dispensed quantity is 52.174g for trial batch manufacturing of 2MIU and 78.261g for trial batch manufacturing of 3MIU, having batch size of 300vials. As 1mg of Colistemethate Sodium is equivalent to 11500IU of Colistemethate Sodium. *As per USP monograph for Colistimethate Sodium "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg. In both CoAs (drug substance manufacture & drug product manufacturer, the Assay (on the as-is basis) given as ≥390µg/mg. The nominal potency of Colistimethate sodium is 12500IU/mg, while the firm claimed as 11500IU/mg. It is not clarified as to how the determined potency claimed as 100% in terms of CBA.*
➢ Since firm has claimed USP specifications. Justify the declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP.	USP states the following Label claim "Colistimethate for Injection contains an amount of Colistimethate Sodium equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of colistin". Same claim has been recommended by the firm. *The firm label claim mentioned in terms of IU, not colistimethate base activity.*
➢ Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.	Submitted CoA mention the potency in terms of both CBA and IU of CMS. CoA again submitted for reference. *As per USP monograph for Colistimethate Sodium "Colistimethate Sodium has a potency equivalent to not less than 390 µg of colistin per mg. In both CoAs (drug substance manufacture & drug product manufacturer, the Assay (on the as-is basis) given as ≥390µg/mg. The nominal potency of Colistimethate sodium is 12500IU/mg, while the firm claimed as 11500IU/mg.*
• As per stability data sheets/reports submitted, the content uniformity test data not provided. Submit	Content Uniformity test will be performed every 10th Batch and data will be submitted accordingly.

content uniformity test data in line with USP general chapter <905> UNIFORMITY OF DOSAGE UNITS.	
• The microbial assay performed is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics—Microbial Assays <81>", particularly the standard dilutions preparation, assay calculation/analysis etc. It is therefore required to clarify and justify as to how the adopted assay procedure and data analysis is in accordance with USP general chapter of microbial assay <81>, both for drug substance & drug product.	As per USP <81>, Microbial Assay should be performed by cylinder plate assay (Diffusion Method), same is adopted by the firm. As far as concentrations are concerned, Concentrations recommended by USP is 1mg/ml and concentration adopted by the firm for low dose is 0.8mg/ml i.e., approximately 1.0mg/ml.
The firm has submitted specifications for the finished drug product as per USP. However, the specifications previously mentioned in Form-5, which was presented in 293rd meeting of registration board, wherein the board deferred the application for submission of stability study data, the specifications have been mentioned as BP. It is therefore advised to submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for drug product specifications revision.	It was typographical error in form 5. Otherwise, specifications of drug product are derived from USP.
• Provide contract manufacturing agreement.	It will be provided.
• Please provide number of vials consumed for one time-point.	As per testing specification 5 vials be used for real time and 5 for accelerated. Total 10 vial till 6Month time point and then 5 vials till claimed shelf life.
• Submit minimum handling capacity for processing of Colistemethate Sodium trial batches (Trial batch bulk volum given 600ml)	It will be provided.

Decision: Deferred for following:

- **The firm has mentioned in stability studies protocol, the Sterility test but the same is not available in stability studies data.**
- **Justify use of non-sterile API (as evident from lack of sterility testing in CoA & import invoice of API) in manufacturing of injectable dosage form as labelling requirements of Colistimethate Sodium USP states "Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms. However, as per manufacturing record of trial batches submitted, the sterilization process not mentioned.**
- **Justification for dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).**
- **Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.**
- **Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.**
- **As per stability data sheets/reports submitted, the content uniformity test data not provided. Submit content uniformity test data in line with USP general chapter <905> UNIFORMITY OF DOSAGE UNITS.**
- **The microbial assay performed is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics—Microbial Assays <81>", particularly the standard dilutions preparation, assay calculation/analysis etc.**
- **Submission of minimum handling capacity for processing of Colistemethate Sodium trial batches (Trial batch bulk volume given 600ml)**

• **Submission of contract manufacturing agreement.**		
499.	Name and address of manufacturer / Applicant	Applicant: M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore. Manufacturer: M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	COLIST INJECTION 3 Million IU Lyophilized Powder for solution for injection/infusion
	Composition	Each vial contains: Colistimethate Sodium …… 3 million IU
	Diary No. Date of R& I & fee	Dy. No 11108 Dated 05-03-2019, Rs. 50,000/- dated 05-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	MHRA approved
	Me-too status	Colistimethate Sodium powder for solution for IV injection/infusion of M/s Mukhtar Enterprises Lahore. Registration No. 094757
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance". DML of M/s Nabiqasim by way of formulation 12-07-2014 & GMP inspection by inspectors dated 03-08-2017 shows the acceptable level of compliance of GMP.
	Remarks of the Evaluator	**Decision of 293rd meeting of Drug Registration Board "Deferred for submission of product development data."**

STABILITY STUDY DATA			
Manufacturer of API	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd.		
API Lot No.	CMSG 1902001		
Description of Pack (Container closure system)	Vial (transparent glass vial, 10ml)		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	360DS01	360DS02	360DS03
Batch Size	300 vials	300 vials	300 vials
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	07-2020	07-2020	07-2020
No. of Batches	03		
Date of Submission	08-03-2022 (6367)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to 307th meeting of DRB held from 08th-10th June,2021, wherein the product Esorid 40mg IV injection has been approved (Contract manufacturing) by referring to the inspection report of M/s Nabiqasim Industries, Karachi for their product Esomax injection, presented in 294th meeting of DRB, held on 9-04-2020. The board decided to approve Esomax 40mg & Esvin 40mg injection (Contract manufacturing). However, it is also mentioned that the scope of the inspection report pertains to the "authenticity of formulation" only.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA (Batch# CMSG 1902001) of API from M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujina Province, China and M/s Nabiqasim Industries (Pvt.) Ltd. Karachi is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Stability study is conducted at Long Term conditions; 25˚C ± 2˚C / 60% ± 5%RH for 36 months and at Accelerated conditions; 40˚C ± 2˚C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36 & 0, 1, 2, 3 & 6 months respectively. Batches:(CMS1707001,CMS1707002, CMS1707003)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of "Written confirmation for active substances exported to EU" dated 22-09-2020 in the name of M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. No.8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, China issued by Fujian, Food & Drug Administration valid till 21-09-2022. It also states that the manufacturing plant complies with the requirements of the Chinese Good Manufacturing practices (= GMP of EU, WHO/ICH Q7). The drug does not have Chinese approval number as it is for export-only. The firm has also provided copy of Drug Manufacturing License No. (Min) 20160089, of M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. No.8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, China valid till 21-09-2025. Details of API are not mentioned in the DML. (DML verifiable online)
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. FXIN1902141D dated 20-03-2019 in the name of

		M/s Nabiqasim Industries (Pvt) Ltd. Karachi, attested by AD (I & E), DRAP Karachi vide No. 1541/21-05-19 dated 24/05/2019 for the import of 0.6kg Colistimethate sodium Non-sterile USP, having batch No. CMSG1902001 from Livzon Group Fuzhou Fuxing pharmaceutical co., Ltd. China.
7.	Protocols followed for conduction of stability study	Submitted
8.	Method used for analysis of FPP	Submitted
9.	Drug-excipients compatibility studies (Where applicable)	According to the firm, the formulation has been developed as per reference product Colomycin 2 M IU (Teva limited, UK), the formulation of colistimethate sodium 2 M IU is qualitatively same as per reference product, hence compatibility study not applicable. The reference product contains no other ingredients except colistimethate sodium.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted Batch Manufacturing record of following 03 Batches: **Batch No.** / **Batch Size** / **Mfg. Date** 360DS01 / 300 vials / 07-2020 360DS02 / 300 vials / 07-2020 360DS03 / 300 vials / 07-2020
11.	Record of comparative dissolution data (where applicable)	Not applicable
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Stability study data for Microbial assay (Bioassay) in the form of inhibition zones measurements provided Firm has submitted record of testing of all batches including COA and summary data sheets.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The product specifications of colistimethate sodium injection based on USP and there is no application of HPLC in testing method because the assay method based on microbial assay therefore compliance record of HPLC software 21 CFR and audit trail reports are not applicable
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR (PEC-XVII)

Deficiency/Observation	**Response by Pharma.**
Provide API stability data as per Zone IV-A conditions. As stability data provided at following conditions: Stability study is conducted at Long Term conditions; 25°C ± 2°C / 60% ± 5%RH for 36 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months at intervals 0, 3, 6, 9, 12, 18, 24, 36 & 0, 1, 2, 3 & 6 months respectively.	Firm submitted Stability studies data as per zone IV-B and stated that it is more stressful than zone IV-A.
Description & solubility specifications of API as provided by the firm, termed as USP. However, these specifications are mentioned as "In-house" by the API	Description and Solubility test are not present in USP Monograph of Colistemethate Sodium.

manufacturer. Also do not exist in USP official monograph of API.	These are additional tests performed by API Manufacturer in addition to USP Tests.
Microbial contamination test/specifications given in API CoA by the firm. However, in analytical testing method of API, the same test not mentioned/provided.	Microbial contamination test is mention in Analytical Test Specification. This test is performed as per <USP 61>. *The firm again provided CoA of API from drug substance manufacturer.*
Provide legible/clear copy of DML of API manufacturer.	Firm submitted legible copy of DML of API manufacturer.
Initiation of stability studies mentioned as July-2020 in stability studies protocols, however, as per Stability study data sheet of trial batches, the initiation date given as 10-08-2020.	
The firm has mentioned in stability studies protocol, the Sterility test but the same has not been mentioned in stability studies data.	As per USP Monograph, Sterility test is not required for API testing. According to USP Colistimethate Sodium must be subjected to further processing during the preparation of injectable dosage forms. *Response of the firm has not clarified the query/observation.*
CoA of reference standard not provided.	Reference standard CoA will be provided. However, API Manufacturer CoA of lot being used in Developmental studies provided.
Justify use of non-sterile API (as evident from lack of sterility testing in CoA & import invoice of API) in manufacturing of injectable dosage form as labelling requirements of Colistimethate Sodium USP states "Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms. However, as per manufacturing record of trial batches submitted, the sterilization process not mentioned.	As per USP Monograph, when label states that Colistimethate Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for Bacterial endotoxins. As per submitted Manufacturing Record and CoA of FPP, BET is performed according to USP. *However, it is stated that as per manufacturing record of trial batches submitted by the firm, there is no details regarding the "further processing".* *USP monograph for Colistimethate sodium include the following labelling requirements:* ***Labeling**—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.* ***Other requirements**—Where the label states that Colistimethate Sodium is sterile; it meets the requirements for Sterility and Bacterial endotoxins under Colistimethate for Injection. Where the label states that Colistimethate Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for Bacterial endotoxins under Colistimethate for Injection.*
In API CoA, the assay limit given "on dried basis" as 11500 IU/mg, that has been used for trial batch calculation. The nominal potency of colistimethate sodium is 12500 IU/mg, which is more than that given for dried basis. Clarification is required regarding batch calculation on dried basis assay. Moreover, loss on	

drying limit mentioned in both API and finished drug product CoA is the same (not more than 7%).	
Clarification is required that how the content uniformity test is in accordance with USP general chapter <905> UNIFORMITY OF DOSAGE UNITS. Also clarify as to why the content uniformity test has not been performed at the required time point during stability studies as evident from the stability data sheets/reports submitted.	Content Uniformity test will be performed every 10th Batch and data will be submitted accordingly.
Contract manufacturing agreement required or not?	It will be provided.
The microbial assay performed is not as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics—Microbial Assays <81>". It is therefore required to clarify and justify as to how the assay procedure followed and data submitted is in accordance with USP general chapter of microbial assay <81>, both for drug substance & drug product.	As per USP <81>, Microbial Assay should be performed by cylinder plate assay (Diffusion Method), same is adopted by the firm. As far as concentrations are concerned, Concentrations recommended by USP is 1mg/ml and concentration adopted by the firm for low dose is 0.8mg/ml i.e., approximately 1.0mg/ml.
The firm has submitted specifications for the finished drug product as per USP. However, the specifications previously mentioned in Form-5, which was presented in 293rd meeting of registration board, wherein the board deferred the application for submission of stability study data, the specifications have been mentioned as BP. It is therefore advised to submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for drug product specifications revision.	It was typographical error in form 5. Otherwise, specifications of drug product are derived from USP.
The number of vials for stability studies of each batch given as 130vials and 60 vials for long term and accelerated stability studies respectively. Please specify, number of vials that has been utilized at each test point with reference to the tests performed.	As per testing specification 5 vials be used for real time and 5 for accelerated. Total 10 vial till 6Month time point and then 5 vials till claimed shelf life.

Decision: Deferred for following:

- **The firm has mentioned in stability studies protocol, the Sterility test but the same is not available in stability studies data.**
- **Justify use of non-sterile API (as evident from lack of sterility testing in CoA & import invoice of API) in manufacturing of injectable dosage form as labelling requirements of Colistimethate Sodium USP states "Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms. However, as per manufacturing record of trial batches submitted, the sterilization process not mentioned.**
- **Justification for dispensed quantity of Colistimethate Sodium against the determined potency in terms of Colistimethate base activity (CBA).**
- **Clarification for considering nomial potency as 11500 IU/mg, for trial batch calculation is required. Since the nominal potency of Colistimethate sodium in literature is given as 12500 IU/mg.**
- **Justification of declared label claim in terms of Colistimethate sodium instead of Colistimethate base activity as recommended by USP as the firm claimed USP specifications for finished drug product.**
- **Initiation of stability studies mentioned as July-2020 in stability studies protocols, however, as per Stability study data sheet of trial batches, the initiation date given as 10-08-2020.**
- **Submitted CoA does not clarify the potency whether in terms of CBA or IU of CMS.**
- **As per stability data sheets/reports submitted, the content uniformity test data not provided. Submit content uniformity test data in line with USP general chapter <905> UNIFORMITY OF DOSAGE UNITS.**

- **The microbial assay performed is not completely as per USP monograph for "Colistimethate for Injection", general chapter "Antibiotics—Microbial Assays <81>", particularly the standard dilutions preparation, assay calculation/analysis etc.**
- **Submission of minimum handling capacity for processing of Colistimethate Sodium trial batches (Trial batch bulk volume given 600ml)**

Case No. 2: Registration applications for local manufacturing of (Human) drugs: (Differential Fee cases)

a. <u>New cases</u>:

500.	Name and address of manufacturer/ Applicant	Shrooq Pharmaceuticals (Pvt) Ltd. 21-Km, Ferozpur Road, Lahore.
	Brand Name + Dosage Form + Strength	Tolteri 4mg capsule
	Composition	Each capsule contains: Tolterodine tartrate.....4mg.
	Diary No. Date of R & I & fee	Dy.No. 513 dated 03-12-2012, Fee Rs: 8,000/-, Date.03-12-2012 (Challan photocopy dated 29-11-2012 provided) Dy.No. 410 dated 31-03-2015, Differential fee: Rs. 12,000 Dated 31-03-2015 (Challan No.0300889 dated 26-03-2015, photocopy provided) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-cholinergic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Detrusitol XL 4 mg, prolonged-release capsules, hard (MHRA approved)
	Me-too status	Urot 4mg capsules by Ciba pharmaceuticals, Karachi. Registration No. 097154
	GMP status	GMP certificate issued on 21-05-2019 based on inspection conducted on 29-01-2019 Panel GMP inspection report dated 23-04-2019 also submitted.
	Remarks of the Evaluator (PEC-XVII)	• Revise label claim/composition, as per reference product as: Each capsule contains: Tolterodine tartrate Sustained Release Pellets 2% Eq. to Tolterodine tartrate… 4mg • The manufacturing outlines need further elaboration as firm has mentioned mixing of dummy pellets with drug pellets in polybag. • GMP inspection report conducted within last 03years is required. • The firm has mentioned tolterodine tartrate sustained release pellets 2%. Please provide source of pellets, stability studies data of 3 batches, GMP certificate of pellets manufacturer, COA of pellets and submit differential fee in case of imported pellets source. • Firm has provided COA, accelerated and long-term stability data for one batch. • Provide evidence of approval of required

		manufacturing facilities by Licensing Division. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Revision of label claim/composition as per reference product as:** **Each capsule contains:** **Tolterodine tartrate Sustained Release Pellets 2% Eq. to Tolterodine tartrate… 4mg** • **Evidence of requisite mixing facilities for sustained release drug pellets with dummy pellets as in the manufacturing outlines provided shown the mixing process performance in polybag.** • **Sustained release pellets source, CoA, stability study data of three batches of pellets and GMP certificate of pellets manufacturer.** • **Most recent GMP audit report from QA & LT division valid within last three years.** • **Submission of applicable fee for composition revision and pellets source approval/fixation as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
501.	Name and address of manufacturer/ Applicant	Masfa Industries (Pvt.) Ltd. 17-Km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	TAMIZOLE Suspension
	Composition	Each 10ml contains: Benzoyl metronidazole……320mg Diloxanide furoate……250mg
	Diary No. Date of R & I & fee	Dy.No. 928 Dated: 01-06-2011, Fee Rs: 8,000/-, Dated 01-06-2011 (photo copy) Dy.No. 80 dated 05-01-2016, Differential fee Rs: 12,000/- Dated 29-12-2015 (photo copy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antiamoebic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 90ml, Rs: 34.00/90ml bottle
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Zolt suspension (Metronidazole benzoate eq to metronidazole: 200mg; Diloxanide Furoate: 250mg) per 10ml of M/s Stanley Pharmaceuticals, Peshawar. Registration No. 076851
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • The generic/me-too has Metronidazole (as metronidazole benzoate) ….200mg Benzoyl metronidazole is the synonym for metronidazole benzoate. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide recent/last GMP inspection report. • Differential fee for two products Peptic-C suspension and Tamizole suspension submitted vide same challan

		No.0515191 dated 23-12-2015. Amount submitted is 24000/- for two products.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submission of most recent GMP audit report conducted within last 03 years.** • **Evidence of approval of requisite manufacturing facilities/ section by Licensig Division, DRAP Islambad.**	
502.	Name and address of manufacturer/ Applicant	Masfa Industries (Pvt.) Ltd. 17-Km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	ECEPHYL cough syrup
	Composition	Each 5ml contains: Acefylline piperazine……...45mg Diphenhydramine HCl……8mg
	Diary No. Date of R & I & fee	Dy.No. 930 Dated: 01-06-2011, Fee Rs: 8,000/-, Dated 01-06-2011 (photo copy) Dy.No. 81 dated 05-01-2016, Differential fee Rs: 12,000/- Dated 29-12-2015 (photo copy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Cough and anti-histamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 60ml, Rs: 35.00/60ml bottle
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Acelyf syrup of M/s Hicon Pharmaceuticals, Peshawar. Registration No. 077431
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • The firm has claimed manufacturer specifications. While the product is non-pharmacopoeial. • Provide evidence of relevant section approval. • Provide recent/last GMP inspection report conducted within last 03 years. • Differential fee of Rs: 24,000/- for two products Ecephyl cough syrup and Otillion suspension submitted vide same challan No.0515190 dated 23-12-2015.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submission of most recent GMP audit report conducted within last 03 years.**	

	• **Evidence of approval of requisite manufacturing facilities/ section by Licensig Division, DRAP Islambad.**	
503.	Name and address of manufacturer/ Applicant	Masfa Industries (Pvt.) Ltd. 17-Km, Sheikhupura Road, Lahore.
	Brand Name + Dosage Form + Strength	PEPTIC-C suspension
	Composition	Each 5ml contains: Famotidine…….10mg
	Diary No. Date of R & I & fee	Dy.No. 4042 Dated: 02-04-2011, Fee Rs: 8,000/-, Dated 01-04-2011 (photo copy) Dy.No. 80 dated 05-01-2016, Differential fee Rs: 12,000/- Dated 29-12-2015 (photo copy), "Duplicate dossier, R & I verified"
	Pharmacological Group	H_2 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 × 60ml, Rs: 68.64.00/60ml bottle
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Dinex suspension of M/s Gulf Pharmaceuticals, National Industrial Zone, Rawat. Registration No. 075050
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • The firm has claimed manufacturer specifications. While the product is non-pharmacopoeial. • Provide evidence of relevant section approval. • Provide recent/last GMP inspection report conducted within last three years. • Differential fee of Rs: 24,000/- for two products Peptic-C suspension and Tamizole suspension submitted vide same challan No.0515191 dated 23-12-2015.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submission of most recent GMP audit report conducted within last 03 years.** • **Submission of approval of requisite manufacturing facilities/ section by Licensig Division, DRAP Islambad.**	
504.	Name and address of manufacturer/ Applicant	Bosch Pharmaceuticals (Pvt.) Ltd., Plot No.221-223, Sector 23, Korangi Industrial Area, Karachi. (DML No. 000350, Plant-I)
	Brand Name + Dosage Form + Strength	QMETEM-P 40mg/ml Injection (I/M)
	Composition	Each 1ml ampoule contains: Artemether ……40mg
	Diary No. Date of R & I & fee	Dy. No. 197 dated 14-03-2011, Fee Rs: 8,000/- (Photo copy), Dy.No. 187 Dated 04-10-2013, Differential fee Rs. 12,000/- dated 25-09-2013 vide challan No. 0003744 Dated 09-09-2013 (Duplicate Dossier, R & I verified)

	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	Firm has claimed manufacturer specifications
	Pack size & Demanded Price	10's & 5's, as per SRO
	Approval status of product in Reference Regulatory Authorities	Strength in the current WHO Model List of Essential Medicines (EML): 80 mg/mL in 1 mL ampoule; other available strengths: 40 mg/mL (paediatric formulation), 60 mg/mL, 100 mg/mL (adult formulation).
	Me-too status	Ufan Injection 40mg/ml of M/s S.J & G Fazul Ellahie (PVt) Ltd. Karachi. Registration No.067038 Misomal 40mg/ml Injection of M/s Tabros pharma, Karachi. Registration No. 066759
	GMP status	GMP compliance inspection report conducted within last three years not provided.
	Remarks of the Evaluator (PEC-XVII)	• Provide Challan copy of differential fee submitted in the year 2013. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • The firm has claimed manufacturer specifications, however monograph available in International Pharmacopoeia. • Provide evidence of approval of relevant section by Licensing Division, DRAP Islamabad. • Provide most recent GMP inspection report conducted within last 03 years.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies/ recommendation by WHO as per decision of Registration Board in its 275th meeting.** • **Latest GMP inspection report conducted within last three years.** • **Revision of finished drug product specifications as per international pharmacopoeia alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
505.	Name and address of manufacturer/ Applicant	Bosch Pharmaceuticals (Pvt.) Ltd., Plot No.209, Sector 23, Korangi Industrial Area, Karachi. (DML No. 000707, Plant-II)
	Brand Name + Dosage Form + Strength	FLUGAL 100mg/50ml (IV infusion)
	Composition	Each 50ml vial contains: Fluconazole USP ……100mg
	Diary No. Date of R & I & fee	Dy. No. 64 dated 07-09-2011 Initial Fee Rs: 8,000/- Dated 16-06-2011 (Challan Photo copy), Differential fee Rs. 12,000/- Dated 16-12-2015 (Photo copy) "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-fungal, triazole derivative
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 Vial, as per PRC policy

	Approval status of product in Reference Regulatory Authorities	Diflucan™ 2 mg/ml solution for infusion (Pfizer Ltd. UK. MHRA approved) (25ml, 50ml, 100ml & 200ml solution for infusion in glass vials)
	Me-too status	Derozol 100mg/50ml Injection of Rotex Pharma (Pvt) Ltd. Islamabad. Registration No. 092334
	GMP status	Routine GMP inspection conducted on 01-12-2021 with conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, M/s Bosch Pharmaceuticals (Pvt.) Limited, located at Plot No.209, Sector-23, Korangi Indusrial Area, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today.
	Remarks of the Evaluator (PEC-XVII)	• Firm has mentioned manufacturer specifications for the finished drug product while official monograph for finished drug product is available. Revise the finished drug product specifications as per official monograph. (Fluconazole in Dextrose injection and Fluconazole in Sodium Chloride injection, USP has separate monographs). • The primary container for the reference product is type I while you have mentioned USP type II. Please calrify? • Provide copy of covering letter for differential fee submission (2015), bearing statistical officer and DRAP R & I stamp. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Firm has manufacturing facilities for Sterile infusion (General) as per GMP certificate issued on 17-07-2020 based on evaluation conducted on 26-06-2019.
	Decision: Approved as per USP specifications with Type I glass vial as primary container. The firm shall submit fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
506.	Name and address of manufacturer/ Applicant	Bosch Pharmaceuticals (Pvt.) Ltd., Plot No.209, Sector 23, Korangi Industrial Area, Karachi. (Plant-II)
	Brand Name + Dosage Form + Strength	FLUGAL 200mg/100ml (IV infusion)
	Composition	Each 100ml vial contains: Fluconazole USP ……200mg
	Diary No. Date of R & I & fee	Dy. No. 54 dated 07-09-2011 Initial Fee Rs: 8,000/- Dated 16-06-2011 (Challan Photo copy), Differential fee Rs. 12,000/- Dated 16-12-2015 (Photo copy) "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-fungal, triazole derivative
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 Vial, as per PRC policy

	Approval status of product in Reference Regulatory Authorities	Diflucan™ 2 mg/ml solution for infusion (Pfizer Ltd. UK. MHRA approved) (25ml, 50ml, 100ml & 200ml solution for infusion in glass vials)
	Me-too status	Konacane 200mg/100ml Infusion of Pharmasol (Pvt) Ltd, Lahore. Registration No. 102577
	GMP status	Routine GMP inspection conducted on 01-12-2021 with conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, M/s Bosch Pharmaceuticals (Pvt.) Limited, located at Plot No.209, Sector-23, Korangi Indusrial Area, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today.
	Remarks of the Evaluator (PEC-XVII)	• Firm has mentioned manufacturer specifications for the finished drug product while official monograph for finished drug product is available. Revise the finished drug product specifications as per official monograph. (Fluconazole in Dextrose injection and Fluconazole in Sodium Chloride injection, USP has separate monographs). • The primary container for the reference product is type I while you have mentioned USP type II. Please clarify? • Provide last/recent GMP inspection report conducted within last 03 years. • Provide copy of covering letter for differential fee submission (2015), bearing statistical officer and DRAP R & I stamp. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Firm has manufacturing facilities for Sterile infusion (General) as per GMP certificate issued on 17-07-2020 based on evaluation conducted on 26-06-2019.
	Decision: Approved as per USP specifications with Type I glass vial as primary container. The firm shall submit fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
507.	Name and address of manufacturer/ Applicant	Bosch Pharmaceuticals (Pvt.) Ltd., Plot No.209, Sector 23, Korangi Industrial Area, Karachi. (Plant-II)
	Brand Name + Dosage Form + Strength	FLUGAL 400mg/200ml (IV infusion)
	Composition	Each 200ml vial contains: Fluconazole USP ……400mg
	Diary No. Date of R & I & fee	Dy. No. 56 dated 07-09-2011 Initial Fee Rs:8,000/- Dated 16-06-2011 (Challan Photo copy), Differential fee Rs.12,000/- Dated 16-12-2015 (Photo copy) "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-fungal, triazole derivative
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 Vial, as per PRC policy

	Approval status of product in Reference Regulatory Authorities	Diflucan™ 2 mg/ml solution for infusion (Pfizer Ltd. UK. MHRA approved) (25ml, 50ml, 100ml & 200ml solution for infusion in glass vials)
	Me-too status	Could not be confirmed
	GMP status	Routine GMP inspection conducted on 01-12-2021 with conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, M/s Bosch Pharmaceuticals (Pvt.) Limited, located at Plot No.209, Sector-23, Korangi Indusrial Area, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today.
	Remarks of the Evaluator (PEC-XVII)	• Firm has mentioned manufacturer specifications for the finished drug product while official monograph for finished drug product is available. Revise the finished drug product specifications as per official monograph. (Fluconazole in Dextrose injection and Fluconazole in Sodium Chloride injection, USP has separate monographs). • The primary container for the reference product is type I while you have mentioned USP type II. Please clarify? • Provide last/recent GMP inspection report conducted within last 03 years. • Provide copy of covering letter for differential fee submission (2015), bearing statistical officer and DRAP R & I stamp. • Provide evidence of drug already approved by DRAP (Generic/me-too) along with brand name, registration number and manufacturer. • Firm has manufacturing facilities for sterile infusion (General) as per GMP certificate issued on 17-07-2020 based on evaluation conducted on 26-06-2019.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting along with Form 5D and differentiall fee, within 6 months.	
508.	Name and address of manufacturer/ Applicant	M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	HEMITHIN tablet
	Composition	Each film-coated tablet contains: Prasugrel Hydrochloride……. 5 mg
	Diary No. Date of R & I & fee	Dy. No. 188 dated 19-07-2010, Rs. 8,000/- dated 19-07-2010 (Photocopy), Dy. No.912 dated 01-08-2016 Differential fee Rs. 12,000/- vide Challan No.0562235 dated 01-08-2016 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-platelet
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per PAC/PRC

	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Prasulet 5mg tablet of M/s Aspin Pharma, Karachi. Registration No. 067507
	GMP status	GMP certificate issued on 16-09-2021, bases on evaluation conducted on 15-09-2021.
	Remarks of the Evaluator (PEC-XVII)	• Revise the label claim as per reference product that is, Each film-coated tablet contains: Prasugrel (as hydrochloride) ……. 5 mg • The firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Tablet Section (General) mentioned in GMP Certificate No.42/2021-DRAP (K) dated 16-09-2021. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications as per following label claim: **Each film coated tablet contains:** **Prasugrel (as Hydrochloride) ……5mg** • **The firm shall Submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
509.	Name and address of manufacturer/ Applicant	M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	HEMITHIN PLUS tablet
	Composition	Each film-coated tablet contains: Prasugrel Hydrochloride……. 10 mg
	Diary No. Date of R & I & fee	Dy. No. 189 dated 19-07-2010, Rs. 8,000/- dated 19-07-2010 (Photocopy), Dy. No.912 dated 01-08-2016, Differential fee Rs. 12,000/- vide Challan No.0562239 dated 01-08-2016 (Photocopy) "Duplicate dossier, R & I Verified"
	Pharmacological Group	Anti-platelet
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Prasulet 10mg tablet of M/s Aspin Pharma, Karachi. Registration No. 067508
	GMP status	GMP certificate issued on 16-09-2021, bases on evaluation conducted on 15-09-2021.
	Remarks of the Evaluator (PEC-XVII)	• Revise the label claim as per reference product that is, Each film-coated tablet contains: Prasugrel (as hydrochloride) ……. 10 mg • The firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Tablet Section (General) mentioned in GMP Certificate No.42/2021-DRAP (K) dated 16-09-2021.

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications and revised label claim as: **Each film coated tablet contains:** **Prasugrel (as Hydrochloride) ……10mg** • **The firm shall Submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
510.	Name and address of manufacturer/ Applicant	M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LIPOTRIM-N Tablet
	Composition	Each film-coated tablet contains: Atorvastatin Calcium….10mg Niacin….500mg
	Diary No. Date of R & I & fee	Dy. No. 43 dated 05-07-2010, Rs. 8,000/- (Photocopy), Dy. No. 912 dated 01-08-2016 Differential fee Rs. 12,000/- vide Challan No.0562230 (Photocopy), (Duplicate dossier, R & I verified)
	Pharmacological Group	HMG-CoA reductase inhibitor + Vitamin B3
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on 16-09-2021, bases on evaluation conducted on 15-09-2021.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting. • Tablet Section (General) mentioned in GMP Certificate No.42/2021-DRAP (K) dated 16-09-2021. • Provide evidence of drug with same composition already registered by DRAP (Me-too/generic) along with proprietary/brand name, registration number and manufacturer.
	Decision: Deferred for following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
511.	Name and address of manufacturer/ Applicant	M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LOOPLITE 10mg Tablet
	Composition	Each tablet contains: Torasemide …...10mg
	Diary No. Date of R & I & fee	Dy. No. 71 dated 11-08-2010, Rs. 8,000/- (Photocopy), Dy. No.912 dated 01-08-2016 Differential fee Rs. 12,000/- vide Challan No.0550751 (Photocopy),

		"Duplicate dossier, R & I verified"
	Pharmacological Group	Loop diuretics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on 16-09-2021, bases on evaluation conducted on 15-09-2021.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of drug with same composition already registered by DRAP (Me-too/generic) along with proprietary/brand name, registration number and manufacturer. • The firm has claimed manufacturer specifications, while official monograph available in USP. • Tablet Section (General) mentioned in GMP Certificate No.42/2021-DRAP (K) dated 16-09-2021. • In MHRA uncoated tablet, while in FDA film-coated tablet available. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit application on Form 5D along with stability studies data as per checklist of 293rd meeting of DRB, in light of the Notification No. 320-DRB/ 2022(PE&R) dated 17th October 2022.** • **Revision of specifications as per official monograph along with fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for product specifications revision.**	
512.	Name and address of manufacturer/ Applicant	M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LOOPLITE 20mg Tablet
	Composition	Each tablet contains: Torasemide …...20mg
	Diary No. Date of R & I & fee	Dy. No. 70 dated 11-08-2010, Rs. 8,000/- dated 11-08-2010 (Photocopy) Dy. No. 912 dated 01-08-2016 Differential fee Rs. 12,000/- vide Challan No.0562234 (Photocopy), (Duplicate dossier, R & I verified"
	Pharmacological Group	Loop diuretics
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on 16-09-2021, bases on evaluation conducted on 15-09-2021.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of drug with same composition already registered by DRAP (Me-too/generic) along with proprietary/brand name, registration number and manufacturer.

		• The firm has claimed manufacturer specifications, while official monograph available in USP. • Tablet Section (General) mentioned in GMP Certificate No.42/2021-DRAP (K) dated 16-09-2021. • In MHRA uncoated tablet, while in FDA film-coated tablet available. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following; • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit drug product stability studies data as per checklist approved by Registration Board in its 293rd meeting along with Form 5D and differentiall fee, within 6 months. .** • **Revision of specifications as per official monograph alongwith fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for product specifications revision.**	
513.	Name and address of manufacturer/ Applicant	M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	NOXAM 4mg tablet
	Composition	Each film-coated tablet contains: Lornoxicam ……4mg (Dispersible tablet)
	Diary No. Date of R & I & fee	Dy.No. 17 dated 01-12-2010, Rs. 15,000/- (Photocopy), Dy. No. dated 27-10-2016 Differential fee Rs. 12,000/- dated 24-10-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	NSAID
	Type of Form	Form 5D
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg - film-coated tablets (Takeda), AGES (Austria)
	Me-too status	Nicam 4mg film-coated tablet of M/s S.J & G Fazul Ellahie, Karachi. Reg.No. 061603
	GMP status	GMP certificate issued on 16-09-2021, bases on evaluation conducted on 15-09-2021.
	Remarks of the Evaluator (PEC-XVII)	• Fee challan for differential fee submission in the year 2016 is required. • In the cover letter of initial submission dated 01-12-2010, the product name mentioned as "Noxam Dispersible tablet", while in application form (Form-5), the product name given is "Noxam tablet. Clarification is required regarding applied formulation. • In the label claim, the product is mentioned as both film-coated & Dispersible tablet, while in formulation provided is for film-coated tablet. Clarification is required regarding applied formulation. • Tablet Section (General) mentioned in GMP Certificate No.42/2021-DRAP (K) dated 16-09-2021.
	Decision: Deferred for following: • **Clarification regarding applied formulation is required since in the cover letter of initial**	

	submission, "Noxam Dispersbile tablet" mentioned, while the label claim provided as film-coated and dispersible tablet. Moreover, formulation given is for film-coated tablet. • **Submission of differential fee challan copy.**	
514.	Name and address of manufacturer/ Applicant	M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	NOXAM Rapid 8mg tablet
	Composition	Each film-coated tablet contains: Lornoxicam …...8mg (Dispersible tablet)
	Diary No. Date of R & I & fee	Dy. No. 16 dated 01-10-2010, Rs. 15,000/-, dated 24-11-2010 (Challan Photocopy), Dy. No. dated 27-10-2016 Differential fee Rs. 12,000/- dated 24-10-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	NSAID
	Type of Form	Form 5D
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo Rapid 8mg - film-coated tablets (Takeda), AGES (Austria)
	Me-too status	Retanox 8mg film-coated tablet Arreta Pharmaceuticals (Pvt) Ltd. Rawalpindi. Registration No. 100677
	GMP status	GMP certificate issued on 16-09-2021, bases on evaluation conducted on 15-09-2021.
	Remarks of the Evaluator (PEC-XVII)	• Fee challan for differential fee submission in the year 2016 is required. • Initial submission verified by R & I Section. • Resubmit application in prescribed format that is Form-5. • Provide evidence of already registered drug (Me-too) for the applied formulation that is dispersible tablet. • Provide evidence that the reference product is in the form of dispersible tablet. • Tablet Section (General) mentioned in GMP Certificate No.42/2021-DRAP (K) dated 16-09-2021.
	Decision: Deferred for following: • **Clarification regarding applied formulation since the label claim provided as film-coated and dispersible tablet.** • **Evidence of applied formulation/drug in dispersible tablet dosage form, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in dispersible tablet dosage form reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Submission of differential fee challan copy.**	
515.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	CLOPAM-0.5mg tablet
	Composition	Each enteric-coated tablet contains: Clonazepam …...0.5mg

	Diary No. Date of R & I & fee	Dy. No. 7931 dated 24-08-2010, Rs. 8,000/- challan dated 18-08-2010 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574076 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Benzodiazepine
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	KLONOPIN tablet 0.5mg (USFDA approved)
	Me-too status	Catier 0.5mg Tablet of M/s Medizan laboratories, Islamabad. Registration No. 102750
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• R & I verified. • At annexure I, the environmental control processing given is for sterile preparations. Please clarify? • Tablet psychotropic section mentioned in the DML renewal report. • Revise label claim as per reference product as: Each tablet contains: Clonazepam……0.5mg • Revise the finished drug product specifications as per official monograph. • Provide most recent GMP inspection report conducted within last three years. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following points: • **Evidence of valid renewal of "Psychotropic tablet" section by Licensing Division.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Revision of label claim as per reference product as follows:** **Each tablet contains:** **Clonazepam…….0.5mg** • **GMP compliance audit report conducted within last 03 years.** • **Fee of Rs. 30,000/- for correction/pre-approval change/ in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
516.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	CLOPAM-2 mg tablet
	Composition	Each enteric-coated tablet contains: Clonazepam …...2mg
	Diary No. Date of R & I & fee	Dy. No. 7935 dated 24-08-2010, Rs. 8,000/- challan dated 18-08-2010 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574075 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Benzodiazepine
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	KLONOPIN tablet 2mg (USFDA approved)
	Me-too status	Catier 2mg Tablet of M/s Medizan laboratories, Islamabad. Registration No. 102751
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• R & I verified. Details incorporated in relevant column above. • At annexure I, the environmental control processing given is for sterile preparations. Please clarify? • Provide evidence of approval of Psychotropic section by Licensing Division, DRAP Islamabad. • Tablet psychotropic section mentioned in the DML renewal report. • Revise label claim as per reference product as: Each tablet contains: Clonazepam…..2mg • Revise the finished drug product specifications as per official monograph. • Provide most recent GMP inspection report conducted within last three years. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following points: • **Evidence of valid renewal of "Psychotropic tablet" section by Licensing Division.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Revision of label claim as per reference product as:** **Each tablet contains:** **Clonazepam…….2mg** • **Most recent GMP compliance audit report conducted within last 03 years.** • **Fee of Rs. 30,000/- for correction/pre-approval change/ in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
517.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	RABEZOLE 20 mg tablet
	Composition	Each enteric-coated tablet contains: Rabeprazole sodium …...20mg
	Diary No. Date of R & I & fee	Dy. No. 7937 dated 24-08-2010, Rs. 8,000/- challan dated 18-08-2010 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574074 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ACIPHEX® (Rabeprazole Sodium) delayed-release enteric coated tablets (USFDA approved)
	Me-too status	Evalep Tablet, 10mg enteric coated by Bryon pharma. Reg. No. 052565

	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• R & I verified. Details incorporated in relevant column above. • At annexure I, the environmental control processing given is for sterile preparations. Please clarify? • The master formulation and manufacturing outlines are not in accordance with the label claim, which is of enteric coated tablets. Revise the master formulation and manufacturing outlines accordingly. • Provide most recent GMP inspection report conducted within last three years. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Firm has claimed USP specifications while finished product monograph is not available in USP or any other pharmacopoeia. API monographs available in USP and JP.
	Decision: Approved with Innovator's specifications. However, registration letter shall be issued upon submission of following documents: • **Revised master formulation and manufacturing outlines in accordance with label claim/composition (enteric coated tablets).** • **GMP audit report conducted within last three years by QA&LT Division.** • **Fee of Rs. 7,500/- for correction/pre-approval change/ in master formulation, manufacturing outliens and drug product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 alongwith verification of fee challans as per decision of 285th meeting.**	
518.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	ARIZOLE 10mg tablet
	Composition	Each enteric-coated tablet contains: Aripiprazole …...10mg
	Diary No. Date of R & I & fee	Dy. No. 7928 dated 24-08-2010, Rs. 8,000/- challan dated 18-08-2010 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574072 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Dopamine partial agonist
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ABILIFY® (aripiprazole) Tablets OTSUKA (USFDA approved with boxed warning)
	Me-too status	Ariscot 10mg Tablets of M/s Scotmann, Islamabad. Registration No. 083485
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• R & I verified. Details incorporated in relevant column above. • Revise the label claim as per reference product as: Each tablet contains:

		Aripiprazole …...10mg • Provide most recent GMP inspection report conducted within last three years. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each tablet contains:** **Aripiprzole…….10mg** • **Registration letter shall be issued upon submission of fee of Rs. 30,000/- for correction/pre-approval change/ in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, verification of fee challans as per decision of 285th meeting along with latest GMP inspection report conducted within last three years by QA&LT Division.**	
519.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	BRAINAGOL-10mg tablet
	Composition	Each enteric coated tablet contains: - Olanzapine….10mg
	Diary No. Date of R & I & fee	Dy. No. 7929 dated 24-08-2010, Rs. 8,000/- dated 24-08-2010 challan dated 18-08-2010 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574073 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Thienobenzodiazepine
	Type of Form	Form 5
	Finished product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved both as un-coated and film-coated tablet. The brand "Zyprexa" tablet (US FDA approved) for oral use. While in MHRA "Zyprexa" tablet are mentioned as coated tablet.
	Me-too status	Oferta film-coated tablet 10mg of M/s AAA Health Pharmaceutical Laboratories, Islamabad. Registration No.101823
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 is not signed by the firm's management. • Revise label claim as per reference product as: Each film-coated tablet contains: Olanzapine…….10mg. • Provide most recent GMP inspection report conducted within last three years. • Equipment list provided is for "sterile preparations". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) section available as per DML renewal inspection dated 08-03-2019.
	Decision: Approved with USP specifiations and revised label claim as: **Each film-coated tablet contains:** **Olanzapine……10mg** • **Registration letter shall be issued upon submission of fee of Rs. 30,000/- for correction/pre-**	

	approval change/ in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, verification of fee challans as per decision of 285th meeting along with latest GMP inspection report conducted within last three years by QA&LT Division.	
520.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DOFARIN 40mg Injection
	Composition	Each 2ml contains: - Drotaverine Hydrochloride….40mg
	Diary No. Date of R & I & fee	Dy. No. 536 dated 28-05-2011, Rs. 8,000/- dated 28-05-2011 challan dated 23-05-2011 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574078 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Three European countries Bulgaria, Romania, Hungary
	Me-too status	Drotamed Injection 40mg/2ml of M/s Medicraft pharmaceuticals, Peshawar. Registration No. 098803
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• The container mentioned is vial, while in reference countries, the container is ampoule. • Revise pharmacological group as "Papaverine & derivatives". • The manufacturing outlines described for aseptic bulk sterile filling in vials, while the applied formulation in liquid injectable. Also fill volume given is 1ml. Please clarify and revise accordingly. • The equipment list provided is for cephalosporin injection section. • Provide most recent GMP inspection report conducted within last three years. • The product is non-pharmacopoeial. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Liquid injectable (General) section available as per DML renewal inspection dated 08-03-2019.
	Decision: Approved with Innovator's Specifications. • **Registration letter shall be issued upon submission of fee of Rs. 30,000/- for correction/pre-approval change/ in formulation in line with reference product as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021, verification of fee challans as per decision of 285th meeting along with latest GMP inspection report conducted within last three years by QA&LT Division.**	
521.	Name and address of manufacturer/ Applicant	M/s Friends Pharma (Pvt) Ltd.31-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	PEPRAZOLE-L 20mg Injection
	Composition	Each vial contains: - Pantoprazole sodium equivalent to Pantoprazole…….20mg

	Diary No. Date of R & I & fee	Dy. No. 502 dated 28-05-2011, Rs. 8,000/- dated 28-05-2011 challan dated 23-05-2011 (Photocopy), Differential fee Rs. 12,000/- vide challan No. 0574079 dated 01-08-2016 (Photocopy), "Duplicate dossier, R & I verified"
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(US FDA approved) PROTONIX® I.V. (Pantoprazole sodium), For Injection: 40 mg of pantoprazole white to off-white freeze-dried powder in a single-dose vial for reconstitution.
	Me-too status	Could not be confirmed
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In the initial challan and cover letter of initial submission, the product mentioned as Peprazole 20mg injection. • Revise the label claim as: Each vial contains: Pantoprazole sodium sesquihydrate lyophilized powder eq. to pantoprazole……20mg • Provide me-too/generic drug product already approved by DRAP along with brand name, registration no and manufacturer. • At Annexure-F, equipment list given is for "Epofen Injection. • Provide most recent GMP inspection report conducted within last three years. • BP for monograph available as Pantoprazole for Injection. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Dry powder lyophilized injectable (General) section available as per DML renewal inspection dated 08-03-2019.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of label claim as per reference product as:** **Each vial contains:** **Pantoprazole sodium sesquihydrate lyophilized powder eq. to pantoprazole……20mg** • **GMP audit report conducted within last three years by QA&LT Division.** • **Revision of drug product specifications as per official monograph.** • **Submission of applicable fee for correction/pre-approval change/ in label claim/composition as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
522.	Name and address of manufacturer/ Applicant	M/s Fredmann Pharmaceuticals, Pvt. Ltd. Plot No. 82/83-B, Old Industrial Area, Mirpur Azad Kashmir.
	Brand Name + Dosage Form + Strength	BEP-LOW 50mg tablet
	Composition	Each tablet contains: Losartan Potassium……...50mg

	Diary No. Date of R & I & fee	Dy. No. 6867 dated 10-09-2012, Rs. 8,000/- dated 07-09-2012 (Photocopy), Dy. No. dated 21-10-2015, Differential fee Rs: 12000/- dated 21-10-2015 vide deposit Slip No. 0525952 (Photocopy). R& I verified
	Pharmacological Group	Angiotensin II receptor antagonist
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	COZAAR® 25mg, 50mg, 100mg (Organon) US FDA approved with box warning as: WARNING: FETAL TOXICITY
	Me-too status	Leupo 50mg tablet of M/s City pharmaceutical laboratories, Karachi. Registration No.102997
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide DRAP R & I cover letter copy of initial submission of application in the year 2012. • Revise the label claim as: Each film-coated tablet contains: Losartan potassium…….50mg • Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications, while official monograph available as per USP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications as per following label claim: **"Each film-coated tablet contains:** **Losartan potassium…….50mg"** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and dosage form from uncoated to film coated tablet, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with latest GMP inspection report conducted within last three years.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
523.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	TRIXOMAP 250mg Injection (IM)
	Composition	Ceftriaxone……. 250 mg
	Diary No. Date of R & I & fee	Dy. No. 49 dated 11-10-2010, Fee Rs. 8,000/- challan dated 06-10-2010 (Photocopy), Dy. No. dated 26-04-2016, Differential fee Rs. 42,000/- vide Challan No.0536999 (Photocopy), "Duplicate dossier, R & I record could not be verified.
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's, As per PAC/PRC

	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Getofin 250mg IM injection Getz Pharma, Karachi. Registration No. 024628
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each vial contains: Ceftriaxone (as Sodium) …...250mg • Sterile Dry Powder for Vial Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.952250381 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Registration Board noted the fact that two applications were submitted for Ceftriaxone 250mg injection whereas R&I section verified only one application and subsequently firm requested for considraton of Ceftriaxone 250mg injection for IV route of administration only. Hence Registration Board rejected the instant application of TRIXOMAP 250mg Injection (IM).	
524.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	TRIXOMAP 250mg Injection (IV)
	Composition	Ceftriaxone……. 250 mg
	Diary No. Date of R & I & fee	Dy. No. 49 dated 11-10-2010, Rs. 8,000/- Challan dated 08-10-2010 (Photocopy), Dy. No. dated 16-03-2015, Differential fee Rs. 12,000/- dated 16-03-2015 vide Challan No.0284842 (Photocopy), Dy. No. dated 21-10-2015, Differential fee Rs: 12000/- dated 21-10-2015 vide challan No. 0296666, Dy. No. dated 26-04-2016, Differential fee Rs: 18000/- dated 26-04-2016 vide challan No.0536995. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's, As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Getofin 250mg IV injection Getz Pharma, Karachi. Registration No. 024629
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporin. • Firm revised label claim as: Each vial contains: Ceftriaxone (as Sodium) …...250mg • Sterile Dry Powder for Vial Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.0451778563 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each vial contains:** **Ceftriaxone (as Sodium) …...250mg** • **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
525.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	TRIXOMAP 500mg Injection (IM)
	Composition	Ceftriaxone……. 500 mg
	Diary No. Date of R & I & fee	Dy. No. 51 dated 11-10-2010, Rs. 8,000/- dated 11-10-2010 (Photocopy),

		Dy. No. dated 16-03-2015 Differential fee Rs. 12,000/- dated 16-03-2015 vide Challan No.0284860 (Photocopy), Dy. No. dated 21-10-2015, Differential fee Rs: 12000/- dated 21-10-2015 vide challan No. 0296665, Dy. No. dated 26-04-2016, Differential fee Rs: 18000/- dated 26-04-2016 vide challan No.0536998. R & I record verified. (Duplicate dossier" R & I diary no. needs confirmation
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's, As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Novaxone 500mg Injection IM of M/s NovaMed Pharmaceuticals, Ferozepur Road Lahore. Registration No. 100875
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each vial contains: Ceftriaxone (as Sodium) …...500mg • Sterile Dry Powder for Vial Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.777054103621 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each vial contains:** **Ceftriaxone (as Sodium) …...500mg** • **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**	

	• **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
526.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	TRIXOMAP 500mg Injection (IV)
	Composition	Ceftriaxone……. 500 mg
	Diary No. Date of R & I & fee	Dy. No. 50 dated 11-10-2010, Rs. 8,000/- dated 11-10-2010 (Photocopy), Dy. No. dated 21-10-2015, Differential fee Rs: 12000/- dated 21-10-2015 vide challan No. 029665, Dy. No. dated 11-04-2016, Differential fee Rs: 30000/- dated 11-04-2016 vide challan No.0520755. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's, As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Cefrre 500mg IV Injection of M/s Arreta Pharmaceuticals, Rawalpindi.Registration No. 099792
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each vial contains: Ceftriaxone (as Sodium) …...500mg • Sterile Dry Powder for Vial Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.52918153722 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each vial contains:** **Ceftriaxone (as Sodium) ……500mg**	

	• **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
527.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	TRIXOMAP 1gm Injection (IM)
	Composition	Ceftriaxone……. 1gm
	Diary No. Date of R & I & fee	Dy. No. 52 dated 11-10-2010, Rs. 8,000/- dated 11-10-2010 (Photocopy), Dy. No. dated 16-03-2015, Differential fee Rs: 12000/- dated 16-13-2015 vide challan No. 0284844, Dy. No. dated 11-04-2016, Differential fee Rs: 30000/- vide Challan No. 0520759 dated 11-04-2016 (Photocopy). "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's, As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Sweft Injection 1gm IM of M/s Avensis, Karachi. Registration No. 100346
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each vial contains: Ceftriaxone (as Sodium) ……1gm • Sterile Dry Powder for Vial Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.70878634176 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.

		• GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each vial contains:** **Ceftriaxone (as Sodium) …...1gm** • **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
528.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	TRIXOMAP 1gm Injection (IV)
	Composition	Ceftriaxone……. 1gm
	Diary No. Date of R & I & fee	Dy. No. 47 dated 11-10-2010, Rs. 8,000/- dated 11-10-2010 (Photocopy), Dy. No. dated 16-03-2015, Differential fee Rs: 12000/- dated 16-13-2015 vide challan No. 0284843, Dy. No. dated 11-04-2016, Differential fee Rs: 30000/- dated 11-04-2016 vide Challan No.0520758. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's, As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Cefmark Injection 1gm IV of M/s Medimarker's, Hyderabad. Registration No. 100388
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each vial contains: Ceftriaxone (as Sodium) ……1gm • Sterile Dry Powder for Vial Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014. • Firm submitted fee of Rs: 25,000/- vide online deposit

		slip No.074643721852 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each vial contains:** **Ceftriaxone (as Sodium) …...1gm** • **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
529.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	FIXOMAP 400mg Capsule
	Composition	Cefixime……. 400mg
	Diary No. Date of R & I & fee	Dy. No. 53 dated 11-10-2010, Rs. 8,000/- dated 11-10-2010 (Photocopy), Dy. No. dated 21-10-2015, Differential fee Rs: 12000/- dated 21-10-2015 vide Challan No. 0296653 Dy.No. dated 27-10-2016, Fee Rs: 30,000/- dated 24-10-2016 vide challan No.0564275 dated 17-10-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	5's, As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA Approved)
	Me-too status	Isocef 400mg capsule of M/s Shrooq Pharmaceuticals, Lahore. Registration No. 040852
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each capsule contains: Cefixime (as trihydrate) ……... 400mg

		• Firm revised finished drug product specifications as approved in 313th meeting of Registration Board and notified vide letter No. No.F.14-1l2022-PEC dated 14-03-2022. • Capsule (Cephalosporin) Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014 addressed to the firm. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.1305152883 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each capsule contains:** **Cefixime (as trihydrate) …….. 400mg** • **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
530.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	FIXOMAP Suspension
	Composition	Cefixime……. 100mg/5ml
	Diary No. Date of R & I & fee	Dy. No. 48 dated 11-10-2010, Rs. 8,000/- dated 11-10-2010 (Photocopy), Dy. No. dated 21-10-2015, Differential fee Rs: 12000/- dated 21-10-2015 vide challan No. 0296659. Dy.No. dated 27-10-2016, Fee Rs: 30,000/- dated 24-10-2016 vide challan No.0564279 dated 17-10-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	60ml, As per PAC/PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA Approved)
	Me-too status	Cefiget 100mg powder for oral suspension of M/s Getz Pharmaceuticals, Karachi. Registration No. 045119.
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020.

		Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate) …… 100mg • Oral Suspension Dry Powder (Cephalosporin) Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014 addressed to the firm. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.47690607651 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each 5ml of reconstituted suspension contains:** **Cefixime (as trihydrate) …… 100mg** • **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
531.	Name and address of manufacturer/ Applicant	Applicant: M/s Maple Pharmaceuticals (Pvt.) Ltd., Plot No. 147, Sector 23, Korangi Industrial Area, Karachi-74900. Manufacturer: PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi-75020.
	Brand Name + Dosage Form + Strength	FIXOMAP DS Suspension
	Composition	Cefixime……. 200mg/5ml
	Diary No. Date of R & I & fee	Dy. No. 54 dated 11-10-2010, Rs. 8,000/- dated 11-10-2010 (Photocopy), Dy. No. dated 01-08-2016, Differential fee Rs: 12000/- dated 01-08-2016 vide Challan No. 0562238 (Photocopy). Dy.No. dated 27-10-2016, Fee Rs: 30,000/- dated 24-10-2016 vide challan No.0564278 dated 17-10-2016. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	60ml, As per PAC/PRC

	Approval status of product in Reference Regulatory Authorities	(US FDA Approved)
	Me-too status	Cefiget DS powder for suspension of M/s Getz Pharmaceuticals, Karachi. Registration No. 045120
	GMP status	GMP certificate issued to PharmEvo (Pvt) ltd. Karachi on 17-09-2020, based on inspection conducted on 16-09-2020. Follow up routine GMP compliance inspection conducted on 26-10-2021 with conclusion as: "Overall, the firm is found operating at a satisfactory level of GMP compliance".
	Remarks of the Evaluator (PEC-XVII)	• Firm revised pharmacological group from antibacterial to third-generation cephalosporins. • Firm revised label claim as: Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate) …… 200mg • Oral Suspension Dry Powder (Cephalosporin) Section has been confirmed by Licensing Division, DRAP Islamabad vide letter No.F.2-1/98-Lic (Vol-II) dated 05-11-2014 addressed to the firm. • Firm submitted fee of Rs: 25,000/- vide online deposit slip No.2756425998 for above revision. However, firm to submit an additional amount of Rs: 50,000/- being contract manufacturing product. Full fee of registration is required as per notifications7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • GMP certificate issued on 16-09-2021 to Maple pharmaceuticals, Karachi, based on evaluation conducted on 15-09-2021.
	Decision: Approved with revised label claim as: **Each 5ml of reconstituted suspension contains:** **Cefixime (as trihydrate) …… 200mg** • **Firm shall submit differential fee of Rs. 50,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s PharmEvo (Pvt) Ltd. Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
532.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	CLARIX 250mg Tablet
	Composition	Each film-coated tablet contains: Clarithromycin……250mg
	Diary No. Date of R & I & fee	Dy. No. 328 dated 25-05-2011, Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy) Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539230 dated 03-05-2016 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Macrolide derivative/Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications

	Pack size & Demanded Price	1×10's, as per PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Clarifah 250mg Tablet of M/s Fahmir Pharma (Pvt) Ltd. Sheikhupura. Registration No. 101543
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP compliance inspection report conducted within last 03 years. • R & I record verified.
	Decision: Approved. • **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
533.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	CLARIX 500mg Tablet
	Composition	Each film-coated tablet contains: Clarithromycin……500mg
	Diary No. Date of R & I & fee	Dy. No. 329 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy) Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539229 dated 03-05-2016 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Macrolide derivative/Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1×10's, As per PRC
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Clarifah 500mg Tablet of M/s Fahmir Pharma (Pvt) Ltd. Sheikhupura. Registration No. 101544
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP compliance inspection report conducted within last 03 years. • R & I record verified.
	Decision: Approved. • **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years by QA&LT Division.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
534.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	MONTEKAST 10mg Tablet
	Composition	Each film-coated tablet contains: Montelukast Sodium eq. to Montelukast……10mg
	Diary No. Date of R & I & fee	Dy. No. 389 dated 28-05-2011 Rs.8000/- dated 28-05-2011, Challan dated 28-05-2011 (Photocopy)

		Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539248 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Cyclopropane acetic acid derivative, Anti-asthmatic, Leukotriene receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1×10's, 1×14's, as per PRC
	Approval status of product in Reference Regulatory Authorities	Montelukast 10mg (as Montelukast Sodium) Film-coated tablets, MHRA approved.
	Me-too status	Dowkast 10mg tablet of M/s Seatle (Pvt) Ltd. Lahore Registration No. 103298
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP compliance inspection report conducted within last 03 years. • Provide finished drug product specifications as per official monograph. • R & I record verified. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. • **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years by QA&LT Division alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
535.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	COARTUM DS Tablet
	Composition	Each tablet contains: Artemether……40mg Lumefantrine…….240mg
	Diary No. Date of R & I & fee	Dy. No. 377 dated 28-05-2011 Rs.8000/- dated 28-05-2011, Challan dated 28-05-2011 (Photocopy) Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539247 (Photocopy). "Duplicate Dossier, R & I verified for Coartom tablet"
	Pharmacological Group	Antimalarial/ antiprotozoal drug
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1×10's, As per PRC
	Approval status of product in Reference Regulatory Authorities	Prequalified by WHO
	Me-too status	Winterm 40mg/240mg tablet of M/s Winthrox laboratories, Karachi. Registration No. 100493
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 is not signed by the firm's management.

		• The initial and differential fee challans submitted for "Coartom tablet" while duplicate dossier provided is for "Coartum DS tablet". • The label claim is of "un-coated" tablet, while master formulation and manufacturing out-lines submitted for film-coated tablet. Please clarify and revise accordingly. • Revise finished drug product specifications as per official monograph (International pharmacopoeia). • Provide evidence of approval of required manufacturing facilities by Licensing Division. • Provide most recent/last GMP compliance inspection report conducted within last 03 years. • Verification of R & I record of initial submission of application required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Clarification regarding applied strength is required from the firm since, as per R & I record, cover letter of initial submission of registration application, initial fee challan and differential fee challan copies submitted, the product applied is "Coartom tablet", while in the duplicate Form-5 submitted by the firm, the product applied is "Coartum DS tablet".** • **Revision of master formulation and manufacturing outlines as per label claim.** • **Revision of finished drug product specifications as per official monograph (International pharmacopoeia).** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Latest GMP inspection report conducted within last three years.**	
536.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZURAFENAC SR Tablet
	Composition	Each sustained release film-coated tablet contains: Diclofenac Sodium……100mg
	Diary No. Date of R & I & fee	Dy. No. 324 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539246 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-rheumatics, Systemics (NSAID)
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	2×10's, 3×10's, As per PRC
	Approval status of product in Reference Regulatory Authorities	VOLTAREN-XR (diclofenac sodium film coated extended release) tablets 100mg, (USFDA Approved) Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	Ajdiclof-SR Tablet 100mg of AJM pharma, Karachi. Registration No. 103065

	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Specify/mention the finished drug product specifications as per official monograph. • Provide most recent/last GMP compliance inspection report conducted within last 03 years. • R & I record verified. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. • **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
537.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZUMAFLAM-P 75mg Tablet
	Composition	Each sugar-coated tablet contains: Diclofenac Potassium……75mg
	Diary No. Date of R & I & fee	Dy. No. 343 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539237 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-rheumatics, Systemics (NSAID)
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	2×10's, As per PRC
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 is not signed by the firm's management. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Provide me-too/generic drug product for the applied formulation (brand name, registration number and firm name). • R & I record verified. • Provide most recent/last GMP compliance inspection report conducted within last 03 years.

	Decision: In order to dispose of new applications of Diclofenac Potassium 75mg tablet, the Board requested Pharmacy Services Divison to intimate PE&R Division regarding provision of safety and efficacy studies approved bv any credible sources and shared by manufcaturers and if no such studies are available than PMA will conduct safety and efficacy trials as per Bio study rules, 2017, as decided by Appellate Board in 162nd meeting.	
538.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZUTEC 150mg Tablet
	Composition	Each film-coated tablet contains: Ranitidine as HCl……150mg
	Diary No. Date of R & I & fee	Dy. No. 346 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539234 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-peptic ulcerants
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1×10's, As per PRC
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Ck-Ran Tablet 150mg of M/s CKD Pharmaceuticals, Karachi. Registration No. 097329
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Revise pharmacological group as "H_2-receptor antagonists". • Form-5 is not signed by the firm's management. • Provide most recent/last GMP compliance inspection report conducted within last 03 years. • R & I record verified. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products.	
539.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	GAVERAL 20mg Capsule
	Composition	Each Capsule contains: Enteric coated pellets of Omeprazole……20mg
	Diary No. Date of R & I & fee	Dy. No. 341 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539233 (Photocopy). (Duplicate Dossier) R& verified
	Pharmacological Group	Anti-peptic ulcerants
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1×14's, As per PRC

	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Parkoprazole Capsule 40mg of M/s Parkar Pharma, Kotri. Registration No. 102817.
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Revise pharmacological group as "Proton pump inhibitor". • Revise manufacturing outlines in accordance with the formulation applied that is for "ready to fill pellets". • Provide most recent GMP inspection report conducted within last 03 years. • Revise label claim as: Each Capsule contains: Omeprazole enteric coated pellets eq to omeprazole ……20mg. • Specify pellets source (manufacturer) and provide CoA of omeprazole pellets, valid GMP certificate of pellets manufacturer, stability data of 03 batches of omeprazole pellets. • Verification of R & I record of initial submission of application required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved as per following label claim: **Each Capsule contains:** **Omeprazole enteric coated pellets eq to omeprazole ……20mg.** • **Firm shall submit documents for pellets source, CoA, stability study data of three batches of pellets and GMP certificate of pellets manufacturer and fee (if import) along with fee of Rs. 7,500 for variation in registration application i.e., correction/change of manufacturing outlines, pharmacological group to "Proton pump inhibitor" as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
540.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	GAVERAL 40mg Capsule
	Composition	Each Capsule contains: Enteric coated pellets of Omeprazole……40mg
	Diary No. Date of R & I & fee	Dy. No. 318 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539242 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-peptic ulcerants
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1×14's, As per PRC
	Approval status of product in Reference Regulatory Authorities	US FDA approved

	Me-too status	Parkoprazole Capsule 40mg of M/s Parkar Pharma, Kotri. Registration No. 102818
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted within last 03 years. • Revise label claim as: Each capsule contains: Omeprazole enteric coated pellets eq to omeprazole ……40mg • Specify pellets source (manufacturer) and provide CoA of omeprazole pellets, valid GMP certificate of pellets manufacturer, stability data of 03 batches of omeprazole pellets. • R & I record verified. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each capsule contains:** **Omeprazole enteric coated pellets eq. to Omeprazole ……40mg** **Registration letter shall be issued upon submission of following:** • **Source of omeprazole pellets, stability study data of 03 batches of omeprazole pellets, CoA, valid GMP certificate of pellets manufacturer.** • **Latest GMP inspection report conducted within last three years along with applicable fee for pellets source fixation (in case of import) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration board further decided to verify fee challans as per decision of 285th meeting.**	
541.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ESOMEZOLE 20mg Capsule
	Composition	Each capsule contains: Enteric coated pellets of Esomeprazole (as Esomeprazole magnesium trihydrate) ……20mg
	Diary No. Date of R & I & fee	Dy. No. 327 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539239 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-peptic ulcerants
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2×7's, As per PRC
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Parko-Eprazole Capsule 20mg of M/s Parkar Pharma, Kotri. Registration No. 102819
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Revise pharmacological group as "Proton pump inhibitor".

		• Provide evidence of approval of relevant section by Licensing Division, DRAP Islamabad. • Provide most recent GMP inspection report conducted within last 03 years. • Revise label claim as: Each capsule contains: Esomeprazole (as Magnesium trihydrate enteric coated pellets) ……20mg • Specify pellets source (manufacturer) and provide CoA of Esomeprazole pellets, valid GMP certificate of pellets manufacturer, stability data of 03 batches of omeprazole pellets. • R & I record verified. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each capsule contains:** **Esomeprazole (as Magnesium trihydrate enteric coated pellets) ……20mg** **Registration letter shall be issued upon submission of following:** • **Source of omeprazole pellets, stability study data of 03 batches of omeprazole pellets, CoA, valid GMP certificate of pellets manufacturer.** • **Latest GMP inspection report conducted within last three years along with applicable fee for pellets source fixation (in case of import) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration board further decided to verify fee challans as per decision of 285th meeting.**	
542.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ESOMEZOLE 40mg Capsule
	Composition	Each capsule contains: Enteric coated pellets of Esomeprazole (as Esomeprazole magnesium trihydrate) ……40mg
	Diary No. Date of R & I & fee	Dy. No. 331 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539228 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-peptic ulcerants
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	2×7's, As per PRC
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Parko-Eprazole Capsule 40mg of M/s Parkar Pharma, Kotri. Registration No. 102820
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted

		within last 03 years. • Revise label claim as: Each capsule contains: Esomeprazole (as Magnesium trihydrate enteric coated pellets) ……40mg • Specify pellets source (manufacturer) and provide CoA of Esomeprazole pellets, valid GMP certificate of pellets manufacturer, stability data of 03 batches of omeprazole pellets. R & I record verified. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each capsule contains:** **Esomeprazole (as Magnesium trihydrate enteric coated pellets) ……40mg** **Registration letter shall be issued upon submission of following:** • **Source of omeprazole pellets, stability study data of 03 batches of omeprazole pellets, CoA, valid GMP certificate of pellets manufacturer.** • **Latest GMP inspection report conducted within last three years along with applicable fee for pellets source fixation (in case of import) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
543.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZUEFIX 400mg Capsule
	Composition	Each capsule contains: Cefixime……400mg
	Diary No. Date of R & I & fee	Dy. No. 339 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539232 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Cephalosporin (3rd generation)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5's, As per PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA Approved)
	Me-too status	Isocef 400mg capsule of M/s Shrooq Pharmaceuticals, Lahore. Registration No. 040852
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Revise the label claim as: Each capsule contains: Cefixime (as trihydrate) ……400mg • Provide most recent GMP inspection report conducted within last 03 years. • Revised finished drug product specifications as

		approved in 313th meeting of Registration Board and notified vide letter No. No.F.14-1l2022-PEC dated 14-03-2022. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each capsule contains:** **Cefixime (as trihydrate) ……400mg** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years along with fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
544.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZUEFIX Dry Suspension (100mg/5ml)
	Composition	Each 5ml suspension contains: Cefixime……100mg
	Diary No. Date of R & I & fee	Dy. No. 322 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539245 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Cephalosporin (3rd generation)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA Approved)
	Me-too status	Cefiget 100mg powder for oral suspension of M/s Getz Pharmaceuticals, Karachi. Registration No. 045119.
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Revise the label claim as: Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate) …… 100mg • Provide most recent GMP inspection report conducted within last 03 years. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml of reconstituted suspension contains:** **Cefixime (as trihydrate) …… 100mg** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years along with fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
545.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZUEFIX DS Dry Suspension (200mg/5ml)

	Composition	Each 5ml suspension contains: Cefixime……200mg
	Diary No. Date of R & I & fee	Dy. No. 330 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539227 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Cephalosporin (3rd generation)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	30ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA Approved)
	Me-too status	Cefiget DS powder for suspension of M/s Getz Pharmaceuticals, Karachi. Registration No. 045120
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Revise the label claim as: Each 5ml of reconstituted suspension contains: Cefixime (as trihydrate) …… 200mg • Provide most recent GMP inspection report conducted within last 03 years. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml of reconstituted suspension contains:** **Cefixime (as trihydrate) …… 200mg** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years along with fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
546.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZURCEF 250mg Capsule
	Composition	Each capsule contains: Cephradine……250mg
	Diary No. Date of R & I & fee	Dy. No. 338 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539238 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Cephalosporin (1st generation)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	12's, As per PRC
	Approval status of product in Reference Regulatory Authorities	Cefradine 250mg Capsules (MHRA approved)
	Me-too status	Dicef 250 mg Capsule by M/s ICI Pharma (#043849)
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted

		within last 03 years. • Revise label claim as: Each capsule contains: Cephradine (anhydrous)……...250mg • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each capsule contains:** **Cephradine (anhydrous)……...250mg** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years along with fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
547.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZURCEF 500mg Capsule
	Composition	Each capsule contains: Cephradine……500mg
	Diary No. Date of R & I & fee	Dy. No-, 344 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539236 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Cephalosporin (1st generation)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	5's, As per PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA Approved)
	Me-too status	Retacef 500mg Capsule of M/s Arreta Pharmaceuticals, Rawalpindi. Registration No. 102738
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted within last 03 years. • Revise label claim as: Each capsule contains: Cephradine (anhydrous)……...500mg • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each capsule contains:** **Cephradine (anhydrous)……...500mg** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years along with fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	

548.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZURCEF Dry Suspension 125mg/5ml
	Composition	Each 5ml suspension contains: Cephradine……125mg
	Diary No. Date of R & I & fee	Dy. No. 334 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539231 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Cephalosporin (1st generation)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	60ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	(US FDA approved with status discontinued)
	Me-too status	Retacef 125mg/5ml Dry Suspensionof M/s Arreta Pharmaceuticals, Rawalpindi. Registration No. 102728
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted within last 03 years. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting as the approval status in USFDA is discontinued. • Revise label claim as: Each 5ml suspension contains: Cephradine (anhydrous)……125mg • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for evidence approval of applied formulation in reference regulatory authorities which were declared/adopted by the Drug Registration Board in its 275th meeting as the approval status in USFDA is discontinued.	
549.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZURCEF Dry Suspension 250mg/5ml
	Composition	Each 5ml suspension contains: Cephradine……250mg
	Diary No. Date of R & I & fee	Dy. No. 320 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551812 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Cephalosporin (1st generation)
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	60ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Cefradine powder for Syrup 250mg/5ml (MHRA approved)

	Me-too status	Retacef 250mg/5ml Dry Suspension of M/s Arreta Pharmaceuticals, Rawalpindi. Registration No. 102727.
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted within last 03 years. • Verification of R & I record of initial submission of application required. • Revise label claim as: Each 5ml of reconstituted suspension contains: Cephradine (anhydrous)……250mg • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 5ml of reconstituted suspension contains:** **Cephradine (anhydrous)……250mg** • **Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years along with fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
550.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ZACTRUM Suspension
	Composition	Each 5ml suspension contains: Trimethoprim……40mg Sulphamethoxazole……200mg
	Diary No. Date of R & I & fee	Dy. No. 336 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539250 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Anti-biotic/Sulfonamide derivative (Co-trimoxazole)
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	50ml,400ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension (MHRA approved)
	Me-too status	Radisulf Oral Suspension of M/s Radiant Pharma, Lahore. Registration No. 074480
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report.
	Decision: Approved. Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years. • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
551.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	HYDRIN Syrup
	Composition	Each 5ml syrup contains:

		Aminophylline…….32mg Diphenhydramine HCl….8mg Ammonium chloride……30mg Menthol……...1mg
	Diary No. Date of R & I & fee	Dy. No. 319 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539243 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Expectorant/antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	120ml,450ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Hydryllin Syrup, M/s Searle, Reg. No. 000016 Each 5ml syrup contains: Aminophylline…….32mg Diphenhydramine HCl….8mg Ammonium chloride……30mg Menthol……...0.98mg
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted within last 03 years. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Verification of R & I record of initial submission of application required. • Provide evidence of me-too/generic drug product already approved by DRAP, with brand name, registration number and manufacturer.
	Decision: Deferred for following; • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as quantity of menthol in applied formulation is different.**	
552.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	VITAPLEX Syrup
	Composition	Each 15ml syrup contains: Thiamine HCl……3 mg Riboflavin Phosphate…3 mg Pyridoxine HCl….2 mg Nicotinamide…23 mg
	Diary No. Date of R & I & fee	Dy. No. 321 dated 25-05-2011 Rs.8000/- dated 24-05-2011, Challan dated 23-05-2011 (Photocopy), Dy.No. dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0539244 (Photocopy). "Duplicate Dossier, R & I verified"
	Pharmacological Group	Vitamins (Vitamin B complex)

	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	60ml, 120ml,450ml, As per PRC
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Liskoplex Syrup (Thiamine HCl 3mg, Riboflavin 3mg, Pyridoxine HCl 2mg, Nicotinamide 23mg) of M/s Lisko Pakistan (Pvt) Ltd. Karachi. Registration No. 003953
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent GMP inspection report conducted within last 03 years. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Approved with following label claim: **"Each 15ml syrup contains:** **Thiamine HCl …… 3 mg** **Riboflavin …… 3 mg** **Pyridoxine HCl ….. 2 mg** **Nicotinamide …… 23 mg"** **Registration letter will be issued upon submission of following:** • **Submission of fee of Rs. 30,000/- for correction/pre-approval change in salt form of Riboflavin as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Latest GMP inspection report conducted within last three years.** • **Verification of fee challans as per decision of 285th meeting of Registration Board.**	
553.	Name and address of manufacturer/ Applicant	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi.
	Brand Name + Dosage Form + Strength	VALSAR-DUE 80/12.5mg tablet
	Composition	Each film coated tablet contains: Valsartan……...80 mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R & I & fee	Dy. No. 1369 dated 09-08-2012, Rs. 8,000/- dated Challan dated 25-07-2012 (Photocopy), Dy. No. dated 22-01-2016, Differential fee Rs. 12,000/- vide challan No. 0514604 dated 07-12-2015 (Photocopy), (Duplicate dossier), R&I verified
	Pharmacological Group	Hypertensive, Congestive heart failure
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, 14's, As per P.R.C
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Co-Diovan® 80/12.5 mg film-coated tablets
	Me-too status	Valhydro-H 80+12.5 Tablet of Ciba pharmaceuticals, Karachi. Registration No. 102901
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator (PEC-XVII)	• Revise the pharmacological group as "Angiotensin II receptor blockers (ARBs) and diuretics".

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Firm shall submit revised pharmacological group as "Angiotensin II receptor blockers (ARBs) and diuretics" along with fee of Rs. 7,500/- for pre-approval change/correction of pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
554.	Name and address of manufacturer/ Applicant	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi.
	Brand Name + Dosage Form + Strength	VALSAR-DUE 160/12.5mg tablet
	Composition	Each film coated tablet contains: Valsartan……...160 mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R & I & fee	Dy. No. 1368 dated 09-08-2012, Rs. 8,000/- dated Challan dated 25-07-2012 (Photocopy), Dy. No. dated 22-01-2016, Differential fee Rs. 12,000/- vide challan No. 0514603 dated 07-12-2015 (Photocopy), (Duplicate dossier) R&I verified
	Pharmacological Group	Hypertensive, Congestive heart failure
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, 14's, As per P.R.C
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Co-Diovan® 160/12.5 mg film-coated tablets
	Me-too status	Hc-Valdil Tablet 160/12.5 of AJM Pharma, Karachi. Registration No. 103056
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator (PEC-XVII)	• Revise the pharmacological group as "Angiotensin II receptor blockers (ARBs) and diuretics". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Firm shall submit revised pharmacological group as "Angiotensin II receptor blockers (ARBs) and diuretics" along with fee of Rs. 7,500/- for pre-approval change/correction of pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
555.	Name and address of manufacturer/ Applicant	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi.
	Brand Name + Dosage Form + Strength	VALSAR-DUE 160/25mg tablet
	Composition	Each film coated tablet contains: Valsartan……...160 mg Hydrochlorothiazide…….25mg
	Diary No. Date of R & I & fee	Dy. No. 1367 dated 09-08-2012, Rs. 8,000/- dated Challan dated 25-07-2012 (Photocopy), Dy. No. dated 22-01-2016, Differential fee Rs. 12,000/- vide challan No. 0514605 dated 07-12-2015 (Photocopy), (Duplicate dossier),R&I verified
	Pharmacological Group	Hypertensive, Congestive heart failure
	Type of Form	Form 5

	Finished product Specification	USP specifications
	Pack size & Demanded Price	10's, 14's, As per P.R.C
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Co-Diovan® 160/25 mg film-coated tablets
	Me-too status	Hc-Valdil Tablet 160/25 of AJM Pharma, Karachi. Registration No. 103057
	GMP status	Updated GMP compliance status is required
	Remarks of the Evaluator (PEC-XVII)	• Revise the pharmacological group as "Angiotensin II receptor blockers (ARBs) and diuretics". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Firm shall submit revised pharmacological group as "Angiotensin II receptor blockers (ARBs) and diuretics" along with fee of Rs. 7,500/- for pre-approval change/correction of pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
556.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals Plot No.4, Street No. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	TALIMUS OINTMENT 0.03%
	Composition	Each gram contains: Tacrolimus monohydrate equivalent to tacrolimus….0.3mg
	Diary No. Date of R & I & fee	Dy. No. 615 dated 28-05-2011, Rs. 8,000/- dated 28-05-2011 (Challan copy not provided) Differential fee Rs. 12,000/- vide challan No.0536652 dated 28-10-2015 (Photocopy) (Duplicate dossier, R & I verified vide Assist.Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020)
	Pharmacological Group	Agents for dermatitis, excluding corticosteroids, atopic dermatitis
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Tacrolimus 0.03% Ointment
	Me-too status	Cromata Ointment 0.03% w/w of M/s Pakistan Pharmaceutical Products (Pvt) Ltd. Karachi. Registration No. 102865
	GMP status	DML renewal inspection conducted on 01-12-2020 and the panel recommended DML renewal of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide initial fee challan copy for the applied product. • Firm revised pharmacological group as "Agents for dermatitis, excluding corticosteroids". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.l • The firm has Cream/Ointment Section (General) as per DML renewal inspection conducted on 01-12-2020, wherein DML renewal recommended by the Panel.
	Decision: Approved. • **Registration letter shall be issued upon submission latest GMP inspection report conducted within last three years., valid within last three years alongwith fee of Rs. 7,500 for variation**	

	in registration application i.e., correction/change of pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
557.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals Plot No.4, Street No. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	HYRON Lotion 3%
	Composition	Each ml contains: Hydroquinone…….30mg
	Diary No. Date of R & I & fee	Dy. No. 446 dated 28-05-2011, Rs. 8,000/- dated 27-05-2011 (Challan copy not provided) Dy. No. dated 28-10-2015, Differential fee Rs. 12,000/- vide challan No. 0536654 (Photocopy), (Duplicate dossier, R & I verified vide Assist.Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020)
	Pharmacological Group	Other dermatologicals
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	DML renewal inspection conducted on 01-12-2020 and the panel recommended DML renewal of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide initial fee challan copy for the applied product. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. Firm provided Eukroma by Leo Pharma, Uk, which couldn't be verified. • Provide me-too/generic drug product approved by DRAP, along with brand name, registration name and manufacturer name. firm provided Melex 3% lotion of Saia pharmaceuticals, Karachi, which could not be verified. • Evidence of approval of required manufacturing facilities by Licensing Division. • The firm has Cream/Ointment Section (General) as per DML renewal inspection conducted on 01-12-2020, wherein DML renewal recommended by the Panel.
	Decision: Deferred for following; **•Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** **•Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as quantity of menthol in applied formulation is different.**	
558.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals Plot No.4, Street No. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	HYRON PLUS CREAM
	Composition	Each ml contains: Hydroquinone…….40mg Glycolic acid……80mg
	Diary No. Date of R & I & fee	Dy. No. 447 dated 28-05-2011, Rs. 8,000/- dated 27-05-2011, Challan dated 27-05-2011 (Photocopy) Dy. No. dated, Differential fee Rs. /- vide challan No. dated (Photocopy),

		(Duplicate dossier, only initial submission verified form R & I vide Assist.Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020. Verification of initial and differential fee challans required)
	Pharmacological Group	Other dermatologicals
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Clariderm-Plus Each gm contains: - Hydroquinone .... 4% w/w, Glycolic Acid .... 8% w/w of M/s Steifel laboratories (Pvt.) Ltd. Registration No. 037851
	GMP status	DML renewal inspection conducted on 01-12-2020 and the panel recommended DML renewal of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of differential fee submission since firm has provided differential fee challan No.0536661 of Metro gel. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Clarification regarding label claim is required as the applied formulation is cream, while the label claim given in "ml". • The firm has Cream/Ointment Section (General) as per DML renewal inspection conducted on 01-12-2020, wherein DML renewal recommended by the Panel.
	Decision: Deferred for following; **•Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** **•Evidence of differential fee submission as differential fee challan No.0536661 submitted is for "Metro gel".** **• Clarification regarding label claim as the applied formulation is cream, while label claim given in "ml".**	
559.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals Plot No.4, Street No. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	ISOTOP PLUS GEL
	Composition	Each gm contains: Isotretinoin…….0.5mg Erythromycin……20mg
	Diary No. Date of R & I & fee	Dy. No. 1198 dated 04-06-2011, Rs. 8,000/- dated 03-06-2011 (Challan copy not provided) Dy. No. dated, Differential fee Rs. /- vide challan No. dated, (Duplicate dossier, R & I verified vide Assist. Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020)
	Pharmacological Group	Retinoid for the treatment of acne, Anti-acne
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Tretocin Gel (Erythromycin …...20mg, Isotretinoin …... 0.50mg) of M/s Dermo tech Pakistan, Lahore. Registration No. 071260

	GMP status	DML renewal inspection conducted on 01-12-2020 and the panel recommended DML renewal of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide initial fee challan copy for the applied product. • Provide evidence of differential fee submission as the Firm has provided differential fee challan No.0536661 for Metro gel. • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • The firm has Cream/Ointment Section (General) as per DML renewal inspection conducted on 01-12-2020, wherein DML renewal recommended by the Panel.
	Decision: Deferred for following; • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of differential fee submission as differential fee challan No.0536661 submitted is for "Metro gel".**	
560.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals Plot No.4, Street No. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	DIMOL EYE DROPS
	Composition	Each ml of ophthalmic solution contains: Timolol maleate equivalent to Timolol…….5mg Dorzolamide HCl eq to Dorzolamide……20mg
	Diary No. Date of R & I & fee	Dy. No. 41 dated 24-05-2011, Rs. 8,000/- (Challan copy not provided) Dy. No. dated, Differential fee Rs. 12,000/- vide challan No.0536670 dated 30-10-2015. (Challan Photocopy), (Duplicate dossier, R & I verified vide Assist. Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020)
	Pharmacological Group	Carbonic anhydrate inhibitors, beta blocking agent, anti-glaucoma preparations and miotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved (COSOPT® (Dorzolamide hydrochloride and timolol maleate ophthalmic solution) containing Dorzolamide 20 mg/ml (2%) and timolol 5 mg/ml (0.5%).
	Me-too status	SyniGan Ophthalmic Solution of M/s Barrett Hodgson, Pakistan, Karachi. Registration No. 055532
	GMP status	DML renewal inspection conducted on 01-12-2020 and the panel recommended DML renewal of the firm.
	Remarks of the Evaluator (PEC-XVII)	• The firm has Sterile Ophthalmic (General) Section as per DML renewal inspection conducted on 01-12-2020, wherein DML renewal recommended by the Panel.
	Decision: Approved with USP specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
561.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals Plot No.4, Street No. S-6, National Industrial Zone, Rawat, Islamabad.

	Brand Name + Dosage Form + Strength	FLORIP EYE DROPS 0.1%
	Composition	Each ml ophthalmic suspension contains: Fluorometholone……1mg
	Diary No. Date of R & I & fee	Dy. No. 38 dated 24-05-2011, Rs. 8,000/- dated 23-05-2011(Fee Challan copy not provided), Dy. No. dated 28-10-2015, Differential fee Rs. 12,000/- vide challan No.0536666 dated 28-10-2015. (Photocopy), (Duplicate dossier, R & I verified vide Assist. Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020)
	Pharmacological Group	Corticosteroids, plain, anti-inflammatory agents
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved FML® (fluorometholone ophthalmic suspension, USP) 0.1% is a sterile, topical anti-inflammatory agent for ophthalmic use.
	Me-too status	Flouramet Ophthalmic Suspension of M/s Pharmasol Pvt ltd. Lahore. Registration No. 090431
	GMP status	DML renewal inspection conducted on 01-12-2020 and the panel recommended DML renewal of the firm.
	Remarks of the Evaluator (PEC-XVII)	• The firm has Sterile Ophthalmic (General) Section as per DML renewal inspection conducted on 01-12-2020, wherein DML renewal recommended by the Panel.
	Decision: Approved. Registration Board further decided to verify fee challans as per decision of 285th meeting.	
562.	Name and address of manufacturer/ Applicant	M/s Panacea Pharmaceuticals Plot No.4, Street No. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	SILON SHAMPOO 2.5%
	Composition	Each ml contains: Selenium Sulfide…….25mg
	Diary No. Date of R & I & fee	Dy. No. 1195 dated 04-06-2011, Rs. 8,000/- dated 03-06-2011. (Fee challan copy dated 03-06-2011provided) Dy. No. dated, Differential fee Rs. /- vide challan No. dated. (Duplicate dossier, R & I verified vide Assist. Director (Reg-II) letter No.F.1-11/2019-Reg-II dated 02-07-2020)
	Pharmacological Group	Other antifungals for topical use
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Selsun Lotion/Shampoo 2.5% Each 100 ml of suspension contains 2.5 g of Selenium Sulphide Ph. Eur.
	Me-too status	SELSUN SUSPENSION of M/s Abbott Pakistan, Karachi. Registration No. 000051
	GMP status	DML renewal inspection conducted on 01-12-2020 and the panel recommended DML renewal of the firm.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of differential fee submission (DRAP R & I stamped cover letter copy of differential fee submission and differential fee challan). • USP monograph available as: Selenium Sulfide Topical Suspension is an aqueous, stabilized suspension of Selenium Sulfide. It contains not less

		than 90.0 percent and not more than 110.0 percent of the labeled amount of SeS2. It contains suitable buffering and dispersing agents. [NOTE—Where labeled for use as a shampoo, it contains a detergent. Where labeled for other uses, it may contain a detergent.] • Firm has provided letter No.F.1-67/2004-Lic dated 17-06-2011 titled as "Grant of additional section – approval thereof" having "Topical preparation" section as evidence of availability of required manufacturing facility for the applied formulation. However, as per DML renewal report dated 01-12-2020, the firm has following sections: 1. Tablet Section (General) 2. Capsule-I Section (General) 3. Capsule-II Section (General) 4. Tablet Section (Psychotropic) 5. Cream/Ointment Section (General) 6. Dry suspension Section (General) 7. Sachet Section (General) 8. Sterile Ophthalmic (Section) 9. Capsule (Ceph) 10. Dry powder for suspension (Ceph).
	Decision: Deferred for: • **Evidence of approval of requisite manufacturing facilitiy by Licensig Division.** • **Evidence of differential fee submission (statistical officer signed/stamped cover letter, fee challan).**	
563.	Name and address of manufacturer/ Applicant	M/s WnsFeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar.
	Brand Name + Dosage Form + Strength	MOOD 200mg tablet
	Composition	Each film-coated extended-release tablet contains: - Carbamazepine…...200mg
	Diary No. Date of R & I & fee	Dy. No. 101 dated 31-12-2010, Rs. 8,000/- dated 01-01-2011 (Challan copy not provided), Differential fee Rs. 12,000/- dated 14-10-2015 vide challan No. 0501571 dated 13-10-2015. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anticonvulsants
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TEGRETOL-XR extended release 100,200,400mg tablet (USFDA approved)
	Me-too status	Epitab XR Tablets 200mg of M/s Werrick pharmaceuticals, Islamabad. Reg. No. 031872
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 not signed by firm management. • R & I record verified. • Provide challan copy of initial fee submission. • The firm has revised label claim in duplicate dossier as "film-coated extended-release tablet" in duplicate dossier since in the cover letters of initial submission and differential fee submission, the firm has not mentioned extended-release tablet. The firm shall therefore submit applicable fee as per notifications 7-

		11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for pre-registration variation. • Provide most recent/last GMP compliance inspection report conducted within last 03 years.
	Decision: Approved. • **Registration letter shall be issued upon submission of fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from film-coated tablet to film coated extended-release tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 alongwith latest GMP inspection report conducted within last three years.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
564.	Name and address of manufacturer/ Applicant	M/s WnsFeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar.
	Brand Name + Dosage Form + Strength	MOOD 400mg tablet
	Composition	Each film-coated extended-release tablet contains: - Carbamazepine…...400mg
	Diary No. Date of R & I & fee	Dy. No. 102 dated 31-12-2010, Rs. 8,000/- dated 01-01-2011 (Challan copy not provided). Differential fee Rs. 12,000/- dated 14-10-2015 vide challan No. 0501570. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anticonvulsants
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TEGRETOL-XR extended release 100,200,400mg tablet (USFDA approved)
	Me-too status	Epitab XR Tablets 400mg of M/s Werrick pharmaceuticals, Islamabad. Reg. No. 031873
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 not signed by firm management. • R & I record verified. • Provide fee challan copy of initial fee submission. • The firm has revised label claim in duplicate dossier as "film-coated extended-release tablet" in duplicate dossier since in the cover letters of initial submission and differential fee submission, the firm has not mentioned extended-release tablet. The firm shall therefore submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for pre-registration variation. • Provide most recent/last GMP compliance inspection report conducted within last 03 years.
	Decision: Approved. • **Registration letter shall be issued upon submission fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from film-coated tablet to film coated extended-release tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 alongwith latest GMP inspection report conducted within last three years.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
565.	Name and address of manufacturer/ Applicant	M/s WnsFeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar.
	Brand Name + Dosage Form + Strength	WINSOTIL tablet
	Composition	Each un-coated tablet contains: - Diphenoxylate Hydrochloride…. 2.5mg

		Atropine Sulphate…….0.025mg
	Diary No. Date of R & I & fee	Dy. No. 91 dated 29-09-2011, Rs. 8,000/- dated 21-09-2011 (Challan copy not provided) Differential fee Rs. 12,000/- dated 14-10-2015 vide challan No.0548753. "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-diarrheral agents/ anti-spasmodic agents
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lomotil tablet, Pfizer (USFDA approved) Each Lomotil tablet contains: 2.5 mg of Diphenoxylate hydrochloride USP (equivalent to 2.3 mg of diphenoxylate) and 0.025 mg of Atropine sulfate USP (equivalent to 0.01 mg of atropine)
	Me-too status	Atox 2.5mg/0.025mg Tablet MBL Pharma, Lasbela. Reg. No. 081015
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 not signed by firm management. • R & I record verified. • Provide challan copy of initial fee submission. • Provide most recent/last GMP compliance inspection report conducted within last 03 years.
	Decision: Rejected since firm does not have approval from CLB for required manufacturing facility of "Tablet (Psychotropic) section".	
566.	Name and address of manufacturer/ Applicant	M/s WnsFeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar.
	Brand Name + Dosage Form + Strength	MEBEWNS 200mg capsule
	Composition	Each modified-release capsule contains: - Mebeverine HCl as extended-release pellets equivalent to Mebeverine HCl ……200mg
	Diary No. Date of R & I & fee	Dy. No. 282 dated 22-11-2011, Rs. 8,000/- dated 22-11-2011 (Challan copy not provided). Differential fee Rs. 12,000/- dated 14-10-2015 vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	anti-spasmodic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Aurobeverine MR 200 mg modified-release capsules, hard)
	Me-too status	Pasmolic MR Capsule 200mg of M/s The Searle Company, Karachi. Reg. No. 103040
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 not signed by firm management. • R & I record verified. • Challan copies of initial and differential fee submission not provided. • As per master formulation/composition, Mebeverine HCl as extended-release pellets (80%), form Vision Pharmaceuticals are to be utilized. Provide CoA, stability study data of pellets for three batches as per Zone IV-A and GMP certificate of pellets source/manufacturer.

		• Provide most recent/last GMP compliance inspection report conducted within last 03 years.
	Decision: Approved. Registration letter shall be issued upon submission pellets source, CoA, stability study data of three batches of pellets and GMP certificate of pellets manufacturer alongwith Latest GMP inspection report conducted within last three years. • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
567.	Name and address of manufacturer/ Applicant	M/s WnsFeild Pharmaceuticals, Plot No.122, Block-A, Phase-V, Industrial Estate Hattar.
	Brand Name + Dosage Form + Strength	TAMOXI 20mg tablet
	Composition	Each film-coated tablet contains: - Tamoxifen (As Citrate) ……...20mg
	Diary No. Date of R & I & fee	Dy. No. 287 dated 25-11-11, Rs. /- 8000/- Dy. No. dated Differential fee Rs. 12,000/- vide challan No. 0548767 dated 14-10-2015. (Duplicate dossier, R & I record of initial and differential fee submission along with fee challans required) R&I verified
	Pharmacological Group	Selective estrogen-receptor modulator
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved (NOLVADEX 10mg & 20mg, uncoated tablet) **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**, Also MHRA approved
	Me-too status	Tamoxidex 20mg Tablet of Pacific pharma, Lahore. Registration No. 098134
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Revise label claim as per reference product as: Each tablet contains: Tamoxifen (As Citrate) ……...20mg, along with revision of master formulation and manufacturing outlines accordingly. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved as per following label claim: **Each tablet contains:** **Tamoxifen (as Citrate) ……...20mg** • **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from film coated to uncoated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with copy of latest GMP inspection report conducted within last three years.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
568.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DYAVISTA 60mg tablet
	Composition	Each Film-coated tablet contains: Raloxifene Hydrochloride…….60 mg
	Diary No. Date of R & I & fee	Dy. No. 206 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011. Dy. No. dated 21-06-2016 Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated.

		(Duplicate dossier, R & I verified".
	Pharmacological Group	Anti-osteoporotic, Selective estrogen receptor modulator
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	EVISTA® 60mg film-coated tablet (USFDA approved with Boxed Warning) Warning: Increased Risk of Venous Thromboembolism and Death from Stroke
	Me-too status	Roxista 60mg Tablets of M/s Genome Pharmaceuticals, Hattar. Registration No. 084619
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report conducted within last 03 years. • Revise master formulation as per label claim, since quantity of Raloxifene base is given. Moreover, film-coating materials not mentioned in master formulation. • Film-coating process not described in the manufacturing outlines/flow chart. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. • **Registration letter shall be issued upon submission latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for variation in registration application i.e., correction/change of master formulation & manufacturing outlines as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
569.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DICLOSTOL tablet (75mg/200mcg)
	Composition	Each modified-release tablet contains: Diclofenac Sodium…….75 mg Misoprostol……200mcg
	Diary No. Date of R & I & fee	Dy. No. 230 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011. Dy. No. dated 21-06-2016 Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated. "Duplicate dossier, R & I verified".
	Pharmacological Group	Anti-rheumatic, NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	2 × 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Arthrotec 75 modified-release tablets (Each tablet consists of a gastro-resistant core containing 75 mg diclofenac sodium surrounded by an outer mantle containing 200 micrograms misoprostol).
	Me-too status	Dolact Tablet 75mg/200mcg of M/s Hiranis Pharmaceuticals, Karachi. Registration No. 103169
	GMP status	Updated GMP compliance status required

	Remarks of the Evaluator (PEC-XVII)	• As per master formulation submitted, the tablet consists of an enteric inner core of Diclofenac Sodium and a film-coated outer core of Misoprostol 1% dispersion. • Provide most recent/last GMP inspection report conducted within last 03 years. • Revise label claim as: Each delayed release tablet contains: Diclofenac Sodium (as gastro-resistant inner core) …...75mg Misoprostol 1% dispersion (as outer core) ……...200mcg • Provide evidence of double layer/core tablet (tablet within tablet) manufacturing facility. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Revision of label claim as per reference product as:** **Each delayed release tablet contains:** **Diclofenac Sodium (as gastro-resistant inner core) …...75mg** **Misoprostol 1% dispersion (as outer core) ……...200mcg** • **Confirmation of required manufacturing equipment i.e. tablet biayered machine for tablet within tablet manufacturing.** • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
570.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DEXIFEN 300mg tablet
	Composition	Each film-coated tablet contains: Dexibuprofen……...300 mg
	Diary No. Date of R & I & fee	Dy. No. 237 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (Challan photocopy), Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated. (Duplicate dossier,- R & I verified".
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Extrofen 300mg tablet of M/s Lahore Chemical and Pharmaceuticals, Lahore. Registration No. 102583
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications, while product is non-pharmacopoeial. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with innovator's specifications.	

	• **Registration letter shall be issued upon submission of Latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
571.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DEXIFEN 400mg tablet
	Composition	Each film-coated tablet contains: Dexibuprofen……...400 mg
	Diary No. Date of R & I & fee	Dy. No. 231 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (Challan photocopy), Dy. No. dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated. (Duplicate dossier, R & I verified".
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Pronsad 400mg Tablet of M/s PDH pharmaceuticals, Lahore. Registration No. 102684
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications, while product is non-pharmacopoeial. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with innovator's specifications. • **Registration letter shall be issued upon submission of Latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
572.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	AMLOMAC 5mg tablet
	Composition	Each film coated tablet contains: - Amlodipine (As Besylate) ……5mg
	Diary No. Date of R & I & fee	Dy. No. 241 dated 25-05-2011 Rs. 8,000/- dated 25-05-2011. Dy. No., dated 21-06-2016 Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated. (Duplicate dossier, R & I verified".
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO

	Approval status of product in Reference Regulatory Authorities	NORVASC – 5 mg uncoated tablets (amlodipine besylate equivalent to 5 mg of amlodipine), USFDA approved.
	Me-too status	Dolimol Tablet 5mg of M/s City Pharmaceuticals, Karachi. Registration No. 103013
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Revise label claim as per reference product as: Each tablet contains: - Amlodipine (As Besylate) ……5mg, along with revision of master formulation and manufacturing outlines. • Revise finished drug product specifications as per official monograph. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with USP specifications and revised label claim as: **Each tablet contains: -** **Amlodipine (As Besylate) ……5mg** • **Registration letter shall be issued upon submission of Latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications & label claim as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
573.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	AMLOMAC 10mg tablet
	Composition	Each film coated tablet contains: - Amlodipine (As Besylate) ……10mg
	Diary No. Date of R & I & fee	Dy. No. 240 dated 25-05-2011 Rs. 8,000/- 25-05-2011. Dy. No. 2636/R&I, dated 21-06-2016, Differential fee Rs. 12,000/- dated vide challan No. dated. (Duplicate dossier, R & I record of initial and differential fee submission along with fee challans required, verified vide AD R-II letter No.F.1-11/2019-Reg-II dated 07-05-2020).
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	NORVASC – 10 mg uncoated tablets (amlodipine besylate equivalent to 10 mg of amlodipine), USFDA approved.
	Me-too status	Dolimol Tablet 10mg of M/s City Pharmaceuticals, Karachi. Registration No. 103014
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Revise label claim as per reference product as: Each tablet contains: -

		Amlodipine (As Besylate) ……10mg, along with revision of master formulation and manufacturing outlines. • Revise finished drug product specifications as per official monograph. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with USP specifications and revised label claim as: **Each tablet contains: -** **Amlodipine (As Besylate) ……10mg** • **Registration letter shall be issued upon submission of Latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications & label claim as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
574.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	MACLOR 4mg tablet
	Composition	Each film-coated tablet contains: Lornoxicam…….4 mg
	Diary No. Date of R & I & fee	Dy. No. 225 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (Challan photocopy), Dy. No., dated 21-06-2016 Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated. (Duplicate dossier, R & I verified".
	Pharmacological Group	Anti-rheumatics (Anti-inflammatory agents)
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg - film-coated tablets (Takeda), AGES (Austria)
	Me-too status	Nicam 4mg film-coated tablet of M/s S.J & G Fazul Ellahie, Karachi. Reg.No. 061603
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • In application form, the product mentioned is Maclor tablet 8mg. • Firm has claimed manufacturer specifications; product is non-pharmacopoeia. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with innovator's specifications. • **Registration letter shall be issued upon submission of Latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and Product name as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
575.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DESTADIN Tablet

	Composition	Each film-coated tablet contains: Desloratadine…….5 mg
	Diary No. Date of R & I & fee	Dy. No. dated 01-06-2011, Rs. 8,000/- dated (), Dy. No., dated 21-06-2016 Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated (Duplicate dossier, R & I record of initial and differential fee submission along with fee challans required).
	Pharmacological Group	Systemic anti-histamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) CLARINEX ®(Desloratadine) Film-coated tablet of Schering Corporation.
	Me-too status	Sltera Tablet 5mg of M/s Welwrd Pharmaceuticals, Hattar. Registration No. 101370
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide DRAP R & I stamped cover letter copies of initial and differential fee submission along with fee challans. • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Deferred for: • **Submission of R&I receiving from DRAP for initial submission of registration application.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Latest GMP inspection report conducted within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
576.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	LEVOXYD 5mg tablet
	Composition	Each film-coated tablet contains: Levocetirizine Dihydrochloride…… 5 mg
	Diary No. Date of R & I & fee	Dy. No. dated 01-06-2011, Rs. 8,000/- dated (), Dy. No. , dated, Differential fee Rs.12,000/- dated vide challan No. 0502343 dated 14-06-2016. (Duplicate dossier, verification of R & I record of initial and differential fee submission along with fee challans required)
	Pharmacological Group	Systemic anti-histamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)
	Me-too status	Merlozine tablet 5mg of M/s Medicraft pharmaceuticals, Peshawar. Registration No. 101383

	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide DRAP R & I stamped cover letter copies of initial and differential fee submission along with fee challans. • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Deferred for: • **Submission of R&I receiving from DRAP for initial submission of registration application.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Latest GMP inspection report conducted within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
577.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	PRASUMAC 10mg Tablet
	Composition	Each film-coated tablet contains: Prasugrel (As hydrochloride) …….10 mg
	Diary No. Date of R & I & fee	Dy. No. 234 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (Challan photocopy), Dy. No. dated 21-06-2016, Differential fee Rs. 12,000/- dated vide challan No. 0502343 dated 14-06-2016. (Duplicate dossier, R & I verified"
	Pharmacological Group	Adenosine Diphosphate receptor antagonist, platelet aggregation inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved with boxed warning. BLEEDING RISK) EFFIENT® 5mg & 10mg film-coated tablet, Daiichi Sankyo.
	Me-too status	Prasulet 5mg Tablet of M/s Aspin pharma, Karachi. Registration No. 067507
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • The firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with innovator's specifications. Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
578.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.

	Brand Name + Dosage Form + Strength	DYCYTO 50mg Tablet
	Composition	Each tablet contains: Cyproterone Acetate…….50 mg
	Diary No. Date of R & I & fee	Dy. No. 219 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011. Dy. No., dated 21-06-2016, Differential fee Rs.12,000/- dated vide challan No. 0502310 dated 13-06-2016. (Duplicate dossier,~~)~~ R & I verified".
	Pharmacological Group	Anti-estrogen
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Mileva Tablet 50mg of Aries pharma, Peshawar. Registration No. 100235
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Revise the pharmacological group from "anti-estrogen" to "Anti-androgens, plain". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (Hormone) Section available as per panel inspection report for grant of additional section dated 18-03-2011 and 20-4-2011. However, formal approval letter not provided.
	Decision: Approved. Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years and revised pharmacological group as "Anti-androgens plain" alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
579.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DICLOMAC Tablet
	Composition	Each dispersible tablet contains: - Diclofenac free acid as diclofenac sodium…….46.5mg
	Diary No. Date of R & I & fee	Dy. No. dated, Rs. 8,000/- dated (), Dy. No. dated 21-06-2016, Differential fee Rs. 12,000/- dated vide challan No. 0502310 dated 13-06-2016. (Duplicate dossier, verification of R & I record of initial and differential fee submission along with fee challans required)
	Pharmacological Group	Gastroprokinetics
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years.

		• Provide DRAP R & I stamped cover letter copies of initial and differential fee submission along with fee challans. • Revise the pharmacological group from "gastroprokinetic" to "non-steroidal anti-inflammatory and anti-rheumatics". • Provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting or else revise label claim/composition as per reference product. The composition and manufacturing outlines should then be revised accordingly. • Provide evidence of drug already approved by DRAP (me-too/generic) along with name, registration number and manufacturer name. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Deferred for: • **Submission of R&I receiving from DRAP for initial submission of registration application.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of pharmacological group from gastroprokinetic" to "non-steroidal anti-inflammatory and anti-rheumatics".** • **Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
580.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	XOOM 50mg Tablet
	Composition	Each film-coated tablet contains: - Diclofenac potassium……...50mg
	Diary No. Date of R & I & fee	Dy. No. 233 dated 25-05-2011 Rs. 8,000/- dated 25-05-2011. Dy. No., dated 21-06-2016, Differential fee Rs.12,000/- dated vide challan No. 0502350 dated 13-06-2016. (Duplicate dossier, R & I verified".
	Pharmacological Group	Analgesic, Anti-inflammatory
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved Cataflam® Tablets
	Me-too status	Dicloflex-P Tablet 50mg of MKB Pharma, Peshawar. Registration No. 102825
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years.

		• Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with USP specifications. Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
581.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	EMTENO Tablet
	Composition	Each film-coated tablet contains: Emtricitabine……...200mg Tenofovir Disoproxil Fumarate……...300 mg
	Diary No. Date of R & I & fee	Dy. No. 235 dated, Rs. 8,000/- dated 25-05-2011. Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated vide challan No. dated 13-06-2016. (Duplicate dossier) R & I verified".
	Pharmacological Group	Antiviral, activity against HIV-1 infection
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) Truvada (Emtricitabine and tenofovir disoproxil fumarate) tablets Gilead Sciences.
	Me-too status	Tenofo-Em Tablets of Genome pharma, Hattar. Registration No. 076090
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Revise finished drug product specifications as per official monograph (International pharmacopoeia). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet (General) Section available as per panel GMP inspection report dated 11-01-2019.
	Decision: Approved with International pharmacopoeia specifications. Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
582.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DYFAMILA Tablet
	Composition	Each tablet contains: Ethinyl estradiol……0.03mg Levonorgestrel……0.15mg
	Diary No. Date of R & I & fee	Dy. No. 220 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011(Challan photocopy), Dy. No. dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated

		(Duplicate dossier, R & I record verified".
	Pharmacological Group	Progestogen
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	28's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)
	Me-too status	Plan Pill Tablet of M/s Aspin pharma Karachi. Registration No. 073533
	GMP status	Updated GMP compliance status required
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Revise pharmacological group as "Progestogens and estrogens, fixed combinations", Hormonal contraceptives for systemic use. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Monograph also available in USP and I.P. • Tablet (Hormone) Section available as per panel inspection report for grant of additional section dated 18-03-2011 and 20-4-2011. However, formal approval letter not provided. •
	Decision: Approved. Registration letter shall be issued upon revision of pharmacological group as "Progestogens and estrogens, fixed combinations", Hormonal contraceptives for systemic use, submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for variation in registration application i.e., correction/change of pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
583.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DYMOSTON 2mg/10mg Tablet
	Composition	Each film-coated tablet contains: Estradiol as Hemihydrate……2mg Dydrogesterone…….10mg (14 orange tablets containing Estradiol Hemihydrate 2mg/tablets and 14 yellow tablets with combination of Estradiol hemihydrate 2mg + Dydrogesterone 10mg)
	Diary No. Date of R & I & fee	Dy. No. 215 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011(Challan photocopy), Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. 0502338 dated (Duplicate dossier, R & I verified".
	Pharmacological Group	Contraceptive, Progestogen
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	28's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Femoston 2/10mg film-coated tablets Each tablet contains 2mg oestradiol (as hemihydrate) or a combination of 2mg oestradiol (as hemihydrate) and 10mg dydrogesterone.
	Me-too status	Couldn't be confirmed

	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide DRAP R & I stamped cover letter copies of initial and differential fee submission along with fee challans. • Tablet (Hormone) Section available as per panel inspection report for grant of additional section dated 18-03-2011 and 20-4-2011. However, formal approval letter not provided.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
584.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	CLARIQUEN DROPS 125mg
	Composition	Each 5ml of reconstitution suspension contains: - Clarithromycin (as taste-mask granules) ...125 mg
	Diary No. Date of R & I & fee	Dy. No. 188 dated 25-05-2011 Rs. 8,000/- dated 25-05-2011. Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated vide challan No. 0562768 dated (Duplicate dossier, R & I verified".
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	25ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Granules for oral suspension)
	Me-too status	Texklar 125mg/5ml Dry Suspension of Rotex pharma Islamabad. Registration No. 097435
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Revise manufacturing outlines/flow chart as per applied formulation (Dry powder suspension) as the submitted manufacturing outlines are for tablet. • Specify/mention source for taste-mask pellets and also provide CoA, accelerated and real-time stability study data of 03 batches and GMP certificate of pellets manufacturer. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • General Section (Dry powder suspension) available as per panel inspection report for grant of additional section dated 18-03-2011 and 20-4-2011. However, formal approval letter not provided.
	Decision: Approved. **Registration letter shall be issued upon submission of following:** • **Revised manufacturing outlines/flow chart as per applied formulation (Dry powder suspension) as the submitted manufacturing outlines are for tablet.** • **Latest GMP inspection report conducted within last three years** • **Taste mask pellets source, CoA, stability study data for three batches and GMP certificate of pellets manufacturer.**	

	• **Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of manufacturing outlines as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Firm shall submit applicable fee for pellets source fixation/approval as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting of Registration Board.**	
585.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DYNIDAZOLE 500mg Suspension
	Composition	Each 5ml of reconstitution suspension contains Secnidazole……...500 mg (Granules for oral suspension)
	Diary No. Date of R & I & fee	Dy. No. 189 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (challan photocopy), Dy. No., dated 21-06-2016, Differential fee Rs.12,000/- dated 21-06-2016 vide challan No. dated (Duplicate dossier, R & I verified".
	Pharmacological Group	amoebicides
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) Oral granules: 2 g secnidazole, in a unit-of-use child-resistant foil packet. SOLOSEC (secnidazole) Oral Granules, 2 g, consists of off-white to slightly yellowish granules containing secnidazole. SOLOSEC is supplied in one unit-of-use child-resistant foil packet of granules in an individual carton. Each packet contains 4.8 g of granules containing 2gm secnidazole.
	Me-too status	Orasecan Dry Powder for Suspension of M/s Valor Pharmaceuticals, Islamabad. Reg.No. 073170
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as the product that is "Solosec" is supplied in one unit-of-use child-resistant foil packet of granules in an individual carton. Each packet contains 4.8 g of granules containing 2gm secnidazole. • Then revise manufacturing outlines/flow chart as per applied formulation as the submitted manufacturing outlines are for tablet. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • General Section (Dry powder suspension) available as per panel inspection report for grant of additional section dated 18-03-2011 and 20-4-2011. However, formal approval letter not provided. • In ANSM, Secnidazole 500 granules is available in sachet form, but the firm has applied for DS in mono dose bottle. Status of 250mg & 500mg microgranules

		in sachet is repealed on 18-09-2015. While 2gm secnidazole in sachet is valid.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/adopted by the Registration Board in its 275th meeting as the USFDA approved product that is "Solosec" is supplied in one unit-of-use child-resistant foil packet of granules in an individual carton. Each packet contains 4.8 g of granules containing 2gm secnidazole.** • **Revision of manufacturing outlines/flow chart as per applied formulation as the submitted manufacturing outlines are for tablet.**	
586.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DYNIDAZOLE 750mg Suspension
	Composition	Each 5ml of reconstitution suspension contains Secnidazole……...750 mg (Granules for oral suspension)
	Diary No. Date of R & I & fee	Dy. No. 195 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (challan photocopy), Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated (Duplicate dossier, R & I verified".
	Pharmacological Group	amoebicides
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) Oral granules: 2 g secnidazole, in a unit-of-use child-resistant foil packet. SOLOSEC (secnidazole) Oral Granules, 2 g, consists of off-white to slightly yellowish granules containing secnidazole. SOLOSEC is supplied in one unit-of-use child-resistant foil packet of granules in an individual carton. Each packet contains 4.8 g of granules containing 2gm secnidazole.
	Me-too status	Prosec 750mg/30ml suspension of Opal laboratories, Karachi. Reg.No. 073706
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Then revise manufacturing outlines/flow chart as per applied formulation as the submitted manufacturing outlines are for tablet dosage form. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • General Section (Dry powder suspension) available as per panel inspection report for grant of additional section dated 18-03-2011 and 20-4-2011. However, formal approval letter not provided. In case of revision of applied formulation, the concerned section approval will be required.
	Decision: Deferred for:	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/adopted by the Registration Board in its 275th meeting as the USFDA approved product that is "Solosec" is supplied in one unit-of-use child-resistant foil packet of granules in an individual carton. Each packet contains 4.8 g of granules containing 2gm secnidazole.** • **Revision of manufacturing outlines/flow chart as per applied formulation as the submitted manufacturing outlines are for tablet.** • **Most recent GMP audit report from QA & LT Division valid within last three years.**	
587.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	LEVOXYD Syrup
	Composition	Each ml contains: Levocetirizine Dihydrochloride…….0.5 mg
	Diary No. Date of R & I & fee	Dy. No. dated, Rs. 8,000/- dated (), Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated (Duplicate dossier, verification of R & I record of initial and differential fee submission along with fee challans required).
	Pharmacological Group	Systemic antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Xyzal 0.5 mg/ml oral solution (MHRA approved)
	Me-too status	Hagel Oral solution (2.5mg/5ml) of Hiranis Pharmaceuticals, Karachi. Reg.No. 098893
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide DRAP R & I stamped cover letter copies of initial and differential fee submission along with fee challans. • The firm has claimed manufacturer specifications. Product is non-pharmacopoeial. • Oral liquid section available as per panel GMP inspection report for grant of GMP certificate conducted on 11-01-2019.
	Decision: Deferred for submission of R&I receiving from DRAP for initial submission of registration application.	
588.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DEXIFEN Suspension
	Composition	Each ml contains: Dexibuprofen…….100 mg
	Diary No. Date of R & I & fee	Dy. No. 236 dated 25-05-2011 Rs. 8,000/- dated 25-05-2011. Dy. No. dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated (Duplicate dossier, R & I verified".
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	60ml, 120ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed

	Me-too status	Dexipro 100mg Suspension of M/s Welmark Pharmaceuticals, Hattar. Reg.No. 076869
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Firm has claimed manufacturer specifications. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Oral liquid section available as per panel GMP inspection report for grant of GMP certificate conducted on 11-01-2019.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/adopted by the Registration Board in its 275th meeting.** • **Latest GMP inspection report conducted within last three years.**	
589.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DACETAM Solution
	Composition	Each ml contains: Levetiracetam…….100 mg
	Diary No. Date of R & I & fee	Dy. No. dated 01-06-2011, Rs. 8,000/- dated 1-06-2011 (Challan photocopy), Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated vide challan No.0502345 dated 14-06-2011. (Duplicate dossier, verification of R & I record of initial and differential fee submission along with fee challans required).
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30ml, 60ml, 120ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Keppra Oral Solution 100mg/ml (USFDA approved)
	Me-too status	Emscot 100mg Oral Solution of M/s Scottman pharmaceuticals, Islamabad. Reg.No. 102640
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide DRAP R & I stamped cover letter copies of initial and differential fee submission along with fee challans. • Revise finished drug product specifications as per official monograph. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Oral liquid section available as per panel GMP inspection report for grant of GMP certificate conducted on 11-01-2019.
	Decision: Deferred for following: • **Submission of R&I receiving from DRAP for initial submission of registration.** • **Revision of finished drug product specifications as per official monograph.**	

590.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DYFOSF 500mg Suspension
	Composition	Each 5ml of reconstitution suspension contains: Fosfomycin Calcium equivalent to Fosfomycin…….500 mg (Granules for oral suspension)
	Diary No. Date of R & I & fee	Dy. No. 194 dated 25-05-2011, Rs. 8,000/- dated 25-05-2011 (Challan photocopy), Dy. No., dated 21-06-2016, Differential fee Rs. 12,000/- dated 21-06-2016 vide challan No. dated (Duplicate dossier, R & I verified".
	Pharmacological Group	Phosphoric Acid Derivative, antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	FOSFOCINA 250mg/5ml powder for oral suspension by M/s LABORATORIOS ERN, S.A. Barcelona, España (Spain Approved)
	Me-too status	Califox 500mg Dry Suspension of M/s Health Care, pharmaceuticals, Multan. Reg.No. 102358
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • In Spain 250mg/5ml strength is approved. • Firm has claimed manufacturer specifications while official monograph available in JP. • Manufacturing outlines provided for tablet dosage form. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • General Section (Dry powder suspension) available as per panel inspection report for grant of additional section dated 18-03-2011 and 20-4-2011. However, formal approval letter not provided.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as approved strength is Sain is 250mg/5ml.** • **Revison of manufacturing outlines as firm has provided manufacturing outlines for tablet dosage form.** • **Revision of finished drug product specifications as per Japanese pharmacopoeia.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and revision of manufacturing outlines as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
591.	Name and address of manufacturer/ Applicant	M/s Dyson Research Laboratories (Pvt.) Ltd., 28-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	DYSOPRIN SR 15mg Capsules
	Composition	Each capsule contains: Cyclobenzaprine HCl as extended-release pellets eq. to Cyclobenzaprine HCl……15mg

	Diary No. Date of R & I & fee	Dy. No. dated 04-04-2012, Rs. 15,000/- dated 04-04-2012 (Challan photocopy), Dy. No., dated 21-06-2016, Differential fee Rs. 85,000/- dated vide challan No. dated (Duplicate dossier, verification of R & I record of initial and differential fee submission along with fee challans required).
	Pharmacological Group	Muscle relaxant, centrally acting agents
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved (AMRIX®, Cyclobenzaprine hydrochloride extended-release capsules)
	Me-too status	Winlex-XR Capsule 15mg of M/s Winthrox laboratories, Karachi. Reg.No. 098617
	GMP status	Updated GMP compliance status required.
	Remarks of the Evaluator (PEC-XVII)	• Provide most recent/last GMP inspection report conducted within last 03 years. • Verification of R & I record of initial submission of application is required. • Provide DRAP R & I stamped cover letter copy differential fee submission along with fee challan. • Specify/mention source of pellets (manufacturer/supplier), CoA of pellets, stability study data of 03 batches and GMP certificate of pellets manufacturer/supplier. • Firm has claimed manufacturer specifications while official monograph available in USP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • General Section (Capsule) available as per panel GMP inspection report conducted on 11-01-2019 for grant of GMP certificate.
	Decision: Deferred for following: • **Submission of R&I receiving from DRAP for initial submission of registration application.** • **Provision of extended-release pellets source (manufacturer), CoA, stability study data of three batches of pellets and GMP certificate of pellets manufacturer.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Submission of applicable fee for pellets source approval/fixation as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
592.	Name and address of manufacturer/ Applicant	Kanel Pharma, Plot No.6, Road SS-3, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	KEMP 4mg Tablet
	Composition	Each tablet contains: Glimepiride ……4mg
	Diary No. Date of R & I & fee	Dy. No.7045 dated 13/07/2012 Rs. 8,000/- dated 02-07-2012 (Statistical Officer verified), Dy. No. 605 dated 26-01-2016, Differential fee Rs. 12,000/- dated 21-01-2016 submitted vide deposit slip No.0136036 dated 20-01-2016 (Original). "Original Dossier"
	Pharmacological Group	Hypoglycemic
	Type of Form	Form-5
	Finished product Specification	USP specifications

	Pack size & Demanded Price	2 × 10's, As fixed by the MoH competent authority
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Uncoated)
	Me-too status	Zoryl 4mg Tablet of M/s Innvotek Islamabad. Registration No. 099264
	GMP status	GMP certificate issued dated 04-06-2020 based on inspection conducted on 03-06-2020.
	Remarks of the Evaluator (PEC-XVII)	• Revise pharmacological group as "sulphonylureas". • Revise master formulation and manufacturing outlines as per label claim/composition of the applied formulation that is un-coated tablet. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet Section (General) available as per GMP certificate dated 04-06-2020.
	Decision: Approved. However, the firm shall submit the fee of Rs. 7,500 for correction/pre-approval change in composition, pharmacological group and manufacturing outlines for uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
593.	Name and address of manufacturer/ Applicant	Kanel Pharma, Plot No.6, Road SS-3, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Paroxin 25mg SR capsule
	Composition	Each capsule contains: Paroxetine (as hydrochloride) ……25mg
	Diary No. Date of R & I & fee	Dy. No.7070 dated 13/07/2012 Rs. 15,000/- dated 02-07-2012 (Statistical Officer verified), Dy. No. 585 dated 26-01-2016, Differential fee Rs. 12,000/- dated 22-01-2016 submitted vide deposit slip No.0136068 dated 22-01-2016 (Original). "Original Dossier"
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's, As fixed by the MoH competent authority
	Approval status of product in Reference Regulatory Authorities	USFDA approved strengths: Tablet and capsule 10, 20, 30, 40mg While extended-release form is in tablet form 12.5mg, 25mg and 37.5mg
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued dated 04-06-2020 based on inspection conducted on 03-06-2020.
	Remarks of the Evaluator (PEC-XVII)	• In initial challan of Rs:15000/-, the product mentioned as Paroxetin 12.5mg SR capsules. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as reference product is in tablet dosage form. • Provide evidence of approval of drug already registered (generic/me-too) by DRAP. • Firm has claimed sustained release capsules, while the formulation provided is not in accordance with label claim for sustained release capsules. • At annexure 1, the composition/label claim given as: Each tablet contains: Paroxetine as hydrochloride….25mg. while the applied formulation is capsule.

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tablet Section (General) available as per GMP certificate dated 04-06-2020.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as reference product is in tablet dosage form.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as quantity of menthol in applied formulation is different.** • **Clarification is required from the firm as in the initial challan of Rs:15000/-, the product mentioned as Paroxetin 12.5mg SR capsules, while applied product is Paroxetin 25mg SR capsule.** • **The master formulation submitted is not in accordance with label claim for sustained release capsules.** • **The composition/label claim given at Annexure-I of the registration dossier as:** **Each tablet contains:** **Paroxetine as hydrochloride….25mg while the applied formulation is capsule.**	
594.	Name and address of manufacturer/ Applicant	Kanel Pharma, Plot No.6, Road SS-3, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	KENSOD 150mg SR capsule
	Composition	Each capsule contains: Diclofenac Sodium Pellets eq. to Diclofenac Sodium …….150
	Diary No. Date of R & I & fee	Dy. No.7084 dated 13/07/2012 Rs. 15,000/- dated 02-07-2012 (Statistical Officer verified), Dy. No. 569 dated 26-01-2016, Differential fee Rs. 12,000/- dated 21-01-2016 submitted vide deposit slip No.0136054 dated 20-01-2016 (Original). "Original Dossier"
	Pharmacological Group	Anti-rheumatic systemic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As fixed by the MoH competent authority
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued dated 04-06-2020 based on inspection conducted on 03-06-2020.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Provide evidence of approval of drug already registered (generic/me-too) by DRAP. • The master formulation/composition provided is for Diclofenac sodium enteric coated pellets, while the formulation applied is sustained release capsule. • The manufacturing outlines are not in accordance with applied formulation as mecobalamin and talcum are mentioned in addition to mixing process etc. • At annexure 3, about list of equipment, production capacity mentioned for cephalosporin capsule section.

		• Provide finished drug product specifications as per official monograph. • Panel inspection report dated 29-08-2012 for grant of DML is provided for Tablet and Capsule sections. • Tablet Section (General) available as per GMP certificate dated 04-06-2020.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as reference product is in tablet dosage form.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as quantity of menthol in applied formulation is different.** • **The master formulation/composition provided is for Diclofenac sodium enteric coated pellets, while the formulation applied is sustained release capsule.** • **The manufacturing outlines are not in accordance with applied formulation as mecobalamin and talcum are mentioned in addition to mixing process etc.** • **At annexure 3 of the registration dossier, regarding equipment list, production capacity mentioned for cephalosporin capsule section.**	
595.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	MOVAX 800mg tablet
	Composition	Each film-coated tablet contains: Metaxalone …...500mg
	Diary No. Date of R & I & fee	Dy. No.526 dated 21-12-2010, Rs. 8,000/- dated 21-12-2010. Dy. No. dated 22-09-2016, Differential fee Rs. 12,000/- vide challan No.0563422 dated 21-09-2016. "Duplicate dossier, & I verified"
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SKELAXIN 400mg & 800mg strengths (USFDA approved)
	Me-too status	Couldn't be confirmed
	GMP status	GMP certificate dated 27-07-2021 issued on the basis of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator (PEC-XVII)	• The label claim given is for 500mg, while the product applied is 800mg tablet (initial, differential fee challans, master formulation is for 800mg tablet). • The reference product is un-coated table, while the firm label claim is for film-coated tablet. Revise label claim as per reference product as; Each tablet contains: Metaxalone……800mg, along with revised master formulation and manufacturing outlines. • The Me-too provided that is Citolin (Reg.No.048336) is of Citicoline (as sodium) tablet 500mg. • Provide evidence of drug product of same composition already approved by DRAP (Me-too/Generic) along with Proprietary name, Registration No. and manufacturer or else submit stability study data as per guidelines of 293rd meeting of Registration Board, along with applicable fee.

		• Firm has claimed manufacturer specifications. However, product official monograph available in USP. • Tablet Section (General) mentioned in Licensing Division letter No.F.1-28/93-Lic dated 30-06-2020 for renewal of DML. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for clarification of applied formulation since the label claim/composition provided is of Metaxalone 500mg tablet, while as per initial & differential fee challans, master formulation, product applied is Metaxalone 800mg tablet. In case generic reference (registered by DRAP) is not available for applied formulation firm shall submit stability studies data as per checklist approved in 293rd meeting along with DFoprm 5D and differential fee within 6 months.	
596.	Name and address of manufacturer/ Applicant	M/s Pharmix Laboratories (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	NEURAL 500mg tablet
	Composition	Each film-coated tablet contains: Citicoline as Sodium…500mg
	Diary No. Date of R & I & fee	Dy. No. 8629 dated 22-09-2010, Rs. 8,000/- dated 22-09-2010. Dy. No. dated 06-12-2018, Differential fee Rs. 12,000/- vide challan No.0796977 dated 28-11-2018. "Duplicate dossier, R & I verified"
	Pharmacological Group	Neurotropics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Citolin 500mg tablet of M/s Global pharmaceuticals, Islamabad. Registration No.048336
	GMP status	GMP certificate dated 27-07-2021 issued on the basis of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities as adopted by the Drug Registration Board in its 275th meeting. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Tablet Section (General) mentioned in Licensing Division letter No.F.1-28/93-Lic dated 30-06-2020 for renewal of DML.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as reference product is in tablet dosage form.	
597.	Name and address of manufacturer/ Applicant	M/s Hansel Pharmaceuticals (Pvt.) Ltd. Plot No.02, Pharma City, 30-Km, Multan Road, Sundar Lahore.
	Brand Name + Dosage Form + Strength	TRICOD tablet 25mg
	Composition	Each tablet contains: Carvedilol……25mg
	Diary No. Date of R & I & fee	Dy. No.575 dated 22-12-2010, Rs. /- dated. Dy. No. dated 26-03-2015, Differential fee Rs. 12,000/- dated 20-03-2015. "Duplicate dossier, R & I verified"
	Pharmacological Group	Alpha/ beta blocker

	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Coreg 3.125 mg, 6.25 mg, 12.5 mg, 25 mg film-coated tablet (USFDA approved)
	Me-too status	Carmos Tablet 25mg of Pakistan pharmaceutical and chemical laboratories, Hyderabad. Reg. No. 101215
	GMP status	cGMP compliance certificate dated 10-10-2019 based on evaluation conducted on 15-05-2019.
	Remarks of the Evaluator (PEC-XVII)	• The initial fee challan of Rs: 8000/- provided is for Tricod tablet 6.25mg. Please provide fee challan for the applied product that is Tricod 25mg tablet. • Provide differential fee challan as submitted in the year 2015. • Revise label claim as per reference product as: Each film-coated tablet contains: Carvedilol……...25mg • Tablet Section (General) available as per cGMP certificate issued on 10-10-2019. • The R & I stamped cover letter copy (Dy.No.575 dated 22-12-2010) has only stamped of statistical officer. The fee is not mentioned. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • The firm submitted fee of Rs: 30,000/- vide online deposit slip No.00623561 for change in composition from 6.25mg to 25mg carvedilol.
	Decision: Approved as per following label claim: **Each film-coated tablet contains:** **Carvedilol……...25mg** **Registration letter wil be issued upon submission of undertaking by the firm with declaration that initial challan of Rs.8,000/- of "Tricod tablet 6.25mg" has neither been used for processing of any other application nor will be used in future.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
598.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	GOPAIN Injection 20mg (2%)
	Composition	Each 1ml injection contains: Lignocaine (as hydrochloride) …….20mg
	Diary No. Date of R & I & fee	Dy. No.21 dated 20-04-2011, Rs: 8000 /- dated 20-04-2011 (Challan photocopy dated 20-04-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535880 dated 24-02-2016. "Duplicate dossier, R & I record of initial submission is verified only. R & I record of differential fee submission not verified."
	Pharmacological Group	anesthetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2ml glass ampoule, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Lidocaine 2 % with preservative Injection, Lidocaine 2% w/v solution for injection

	Me-too status	Adcaine Injection (Each 1ml injection contains Lidocaine HCl….20mg) of M/s Ameer & Adnan pharmaceuticals, Lahore. Registration No. 078638
	GMP status	Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976. • R & I record of initial submission is verified only. R & I record of differential fee submission could not be verified as communicated by the R & I section. However, differential fee challan (No.0535880) photocopy dated 24-02-2016 submitted. • Revise label claim as: Each 2ml of solution for injection contains: Lidocaine hydrochloride……40mg • Lidocaine 2% with preservative Injection is used as a local anaesthetic when injected subcutaneously. This solution is not intended for use intravenously. Solutions of lidocaine, which contain preservatives, should not be used for spinal, epidural, caudal or intravenous regional anaesthesia. Lidocaine solution for injection is indicated for use in infiltration anaesthesia, intravenous regional anaesthesia and nerve blocks. In MHRA, variety of route of administration are given depending upon the intended purpose. Such as in ventricular arrhythmias both IV bolus and IV infusion are mentioned. While the IM route is also given in specific circumstances (in case ECG monitoring is not available). For local anesthesia (local infiltration, spinal, epidural or caudal, paracervical block for obstetric analgesia (including abortion). The preservative-free injection label given as “For infiltration and Nerve block including caudal and epidural use” The injection containing preservative, label is given as “For injection and nerve block” Not for epidural and caudal use. Contains preservative. • Revise finished drug product specifications as per official monograph.

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Verification of differential fee submission.** • **Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021.** • **Revision of label claim as:** **Each 2ml of solution for injection contains:** **Lidocaine hydrochloride……40mg** • **Revision of finished drug product specifications as per official monograph.** • **Evidence of approval of requisite manufacturing facilities by Licensing Division.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
599.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	TRAXOFIN 250mg Injection (IM)
	Composition	Each vial contains: Ceftriaxone (as Sodium) …….250mg
	Diary No. Date of R & I & fee	Dy. No. dated 21-05-2011, Rs: 8000 /- dated 20-05-2011 (Challan photocopy dated 20-05-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535881 dated 24-02-2016. "Duplicate dossier, R & I record of initial application submission and differential fee submission could not be verified."
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Getofin 250mg IM injection Getz Pharma, Karachi. Registration No. 024628
	GMP status	Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976. • R & I record of initial submission of application form and differential fee submission could not be verified as communicated by the R & I section.

		• However, differential fee challan (No.0535881) photocopy dated 24-02-2016 provided. • Specify finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Verification of R & I record of initial submission of registration application and differential fee submission.** • **Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Evidence of approval of requisite manufacturing facilities by Licensing Division.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
600.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	TRAXOFIN 500mg Injection (IM)
	Composition	Each vial contains: Ceftriaxone (as Sodium) …….500mg
	Diary No. Date of R & I & fee	Dy. No. dated 21-05-2011, Rs: 8000 /- dated 20-05-2011 (Challan photocopy dated 20-05-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535883 dated 24-02-2016. "Duplicate dossier, R & I record of initial application submission and differential fee submission could not be verified."
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Novaxone 500mg Injection IM of M/s NovaMed Pharmaceuticals, Ferozepur Road Lahore. Registration No. 100875
	GMP status	Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Routine GMP inspection report dated 05th & 06th August, 2021 concluded as: Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

		• R & I record of initial submission of application form and differential fee submission could not be verified as communicated by the R & I section. • However, differential fee challan (No.0535883) photocopy dated 24-02-2016 submitted. • Specify finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Verification of R & I record of initial submission of registration application and differential fee submission.** • **Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Evidence of approval of requisite manufacturing facilities by Licensing Division.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
601.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	TRAXOFIN 1gm Injection (IM)
	Composition	Each vial contains: Ceftriaxone (as Sodium) …….1gm
	Diary No. Date of R & I & fee	Dy. No.22 dated 20-04-2011, Rs: 8000 /- dated 20-04-2011 (Challan photocopy dated 20-04-2011 provided) Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535878 dated 24-02-2016. "Duplicate dossier, R & I record of initial application submission is verified only. R & I record of differential fee submission not verified."
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Sweft Injection 1gm IM of M/s Avensis, Karachi. Registration No. 100346
	GMP status	Updated cGMP compliance status is required.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent GMP inspection report conducted within last 03 years. • R & I record of initial submission of application is verified only. • R & I record of differential fee submission could not be verified as communicated by the R & I section. • Specify finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Verification of differential fee submission.**	

	• **Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Evidence of approval of requisite manufacturing facilities by Licensing Division.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
602.	Name and address of manufacturer/ Applicant	M/s Pak Risen Pharmaceuticals, Plot No. 3, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	CD-3 Injection 5mg/ml (oral)
	Composition	Each 1ml injection contains: Cholecalciferol …….5mg
	Diary No. Date of R & I & fee	Dy. No.641 dated 13-07-2012, Rs: 8000 /- dated 13-07-2012 (Challan copy not available). Dy. No.468 dated 24-03-2016, Differential fee Rs: 12,000/- dated 24-02-2016 vide challan No.0535882 dated 24-02-2016. "Duplicate dossier, R & I record of initial application submission is verified only. R & I record of differential fee submission not verified."
	Pharmacological Group	Vitamin D
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Sweft Injection 1gm IM of M/s Avensis, Karachi. Registration No. 100346
	GMP status	Updated cGMP compliance status is required.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent GMP inspection report conducted within last 03 years. • R & I record of initial submission of application is verified only. • R & I record of differential fee submission could not be verified as communicated by the R & I section. • Specify finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Verification of differential fee submission.** • **Production of the firm is suspended vide QA & LT Division letter No.F.4-2/2006-QA (Vol-I) dated 23-08-2021 and by the CLB in its 283rd meeting held on 28-10-2021.** • **Revision of finished drug product specifications as per official monograph (USP).** • **Evidence of approval of requisite manufacturing facilities by Licensing Division.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
603.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	LEVITAM 250mg tablet
	Composition	Each film-coated tablet contains: Levetiracetam…….....250mg
	Diary No. Date of R & I & fee	Dy. No. 172 dated 11-01-2012, Rs. 8,000/- challan dated 06-01-2012 (Photocopy),

		Dy. No. 25863 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955333 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Anticonvulsant & antiepileptic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Levepil 250mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087690
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Firm has provided undertaken that the product (Levitam 250mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
604.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	LEVITAM 500mg tablet
	Composition	Each film-coated tablet contains: Levetiracetam…….....500mg
	Diary No. Date of R & I & fee	Dy. No. 168 dated 11-01-2012, Rs. 8,000/- challan dated 06-01-2012 (Photocopy), Dy. No. 25864 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955332 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Anticonvulsant & antiepileptic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Levepil 500mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087691
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Firm has provided undertaken that the product (Levitam 500mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	

605.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	LEVITAM Oral Solution (100mg/ml)
	Composition	Each 5ml contains: Levetiracetam…….....500mg
	Diary No. Date of R & I & fee	Dy. No. 169 dated 11-01-2012, Rs. 8,000/- challan dated 06-01-2012 (Photocopy), Dy. No. 25862 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955334 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Anticonvulsant & antiepileptic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Keppra Oral Solution 100mg/ml (USFDA approved)
	Me-too status	Emscot 100mg Oral Solution of M/s Scottman pharmaceuticals, Islamabad. Reg.No. 102640
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid (General) Section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • The product mentioned in DRAP R & I cover letter of differential fee submission and differential fee challan is Livatam syrup 10mg. The firm termed it as "typo error". • R & I record for differential fee submission in original available (DRAP R & I cover letter and fee challan, statistical officer verified). • Firm has provided undertaken that the product (Levitam syrup) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
606.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	VOSTA 10mg tablet
	Composition	Each film-coated tablet contains: Rosuvastatin (as calcium) …….....10mg
	Diary No. Date of R & I & fee	Dy. No. 5011 dated 06-06-2012, Rs. 8,000/- challan dated 05-06-2012 (Challan Photocopy dated 05-06-2012), Dy. No. 25871 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955350 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Statins belong to Lipid Regulating drugs
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)

	Me-too status	Novitin 10mg Tablet, 3S Pharmaceuticals, Lahore. Registration No. 100542
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.y
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • In initial fee challan (Rs:8000/-), the product mentioned as Vosta 10mg (Rosuvastatin calcium), while in duplicate Form 5 submitted, the label claim/composition is revised as: Each film-coated tablet contains: Rosuvastatin (as calcium) ….....10mg • The firm submitted fee of Rs: 30,000/- vide online deposit slip No.954054683387 for above revision in label claim. • Firm has provided undertaken that the product (Vosta 10mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
607.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	VOSTA 20mg tablet
	Composition	Each film-coated tablet contains: Rosuvastatin (as calcium) ….....20mg
	Diary No. Date of R & I & fee	Dy. No. 5013 dated 06-06-2012, Rs. 8,000/- challan dated 05-06-2012 (Challn Photocopy dated 05-06-2012) Dy. No. 25872 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955979 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Statins belong to Lipid Regulating drugs
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)
	Me-too status	Novitin 20mg Tablet, 3S Pharmaceuticals, Lahore. Registration No. 100543
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • In initial fee challan (Rs:8000/-), the product mentioned as Vosta 20mg (Rosuvastatin calcium), while in duplicate Form 5 submitted, the label claim/composition revised as: Each film-coated tablet contains: Rosuvastatin (as calcium) ….....20mg

		• The firm submitted fee of Rs: 30,000/- vide online deposit slip No.38873900 for above revision in label claim. • Firm has provided undertaken that the product (Vosta 20mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
608.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	FORPRIDE Tablet 1mg
	Composition	Each film-coated tablet contains: Glimepiride ….....1mg Metformin hydrochloride……500mg
	Diary No. Date of R & I & fee	Dy. No. 5638 dated 23-05-2011, Rs. 8,000/- challan dated 16-05-2011 (Photocopy), Dy. No. 25873 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955338 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	antidiabetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Limi Tablets 1/500mg of M/s Dyson research laboratories, Lahore. Registration No. 078843
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Provide evidence of applied formulation in reference regulatory authorities as adopted by Registration Board in its 275th meeting. • The product is non-pharmacopoeial. • Registration Board in its 282nd meeting held on 14th – 15th May, 2018 decided to issue show cause notice to all registered/ already marketed drug products containing applied formulation (Glimepiride/Metformin), on the basis that this drug product is not available in any of the reference regulatory authority as specified by Registration Board in its 275th meeting. • Firm has provided undertaken that the product (Forpride 1mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted/declared by Registration Board in its 275th meeting.	
609.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.

	Brand Name + Dosage Form + Strength	FORPRIDE Tablet 2mg
	Composition	Each film-coated tablet contains: Glimepiride ….....2mg Metformin hydrochloride……500mg
	Diary No. Date of R & I & fee	Dy. No. 5637 dated 23-05-2011, Rs. 8,000/- challan dated 16-05-2011 (Photocopy), Dy. No. 25874 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955337 dated 13-11-2019 (Original), "Duplicate dossier"– R & I verified"
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Limi Tablets 2/500mg of M/s Dyson research laboratories, Lahore. Registration No. 078841
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Provide evidence of applied formulation in reference regulatory authorities as adopted by Registration Board in its 275th meeting. • The product is non-pharmacopoeial. • Registration Board in its 282nd meeting held on 14th – 15th May, 2018 decided to issue show cause notice to all registered/ already marketed drug products containing applied formulation (Glimepiride/Metformin), on the basis that this drug product is not available in any of the reference regulatory authority as specified by Registration Board in its 275th meeting. • Firm has provided undertaken that the product (Forpride 2mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted/declared by Registration Board in its 275th meeting.	
610.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	SITOKOL Tablet 500mg
	Composition	Each film-coated tablet contains: Citicoline (as Sodium) ….....500mg
	Diary No. Date of R & I & fee	Dy. No. 5629 dated 23-05-2011, Rs. 8,000/- challan dated 20-05-2011 (Photocopy), Dy. No. 25853 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955346 dated 13-11-2019 (Original), "Duplicate dossier," R & I verified"
	Pharmacological Group	Psychotherapeutic drug

	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Citolin 500mg tablet of M/s Global pharmaceuticals, Islamabad. Registration No.048336
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Provide evidence of applied formulation in reference regulatory authorities as adopted by Registration Board in its 275th meeting. • Revise pharmacological group as "Other psychostimulants and nootropics". • The product is non-pharmacopoeial. • Firm has provided undertaken that the product (sitokol 500mg tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities which were adopted/declared by Registration Board in its 275th meeting.** • **Revision of pharmacological group as "Other psychostimulants and nootropics".**	
611.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	SITOKOL Syrup (500mg/5ml)
	Composition	Each 5ml contains: Citicoline (as Sodium) ….....500mg
	Diary No. Date of R & I & fee	Dy. No. 5628 dated 23-05-2011, Rs. 8,000/- challan dated 20-05-2011 (Photocopy), Dy. No. 25851 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955345 dated 13-11-2019 (Original), "Duplicate dossier," R & I verified"
	Pharmacological Group	Psychotherapeutic drug
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Somazine 100 mg / ml oral solution. (CIMA Spain approved)
	Me-too status	E-Citi Syrupof M/s English pharmaceuticals, Lahore. Registration No. 100526
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid (General) section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • The product is non-pharmacopoeial. • Firm has provided undertaken that the product (sitokol

		syrup) has never been discussed or deferred in any meeting and that given information are true. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's Specifications. • **The firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
612.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	GUIDE SR Capsule 150mg
	Composition	Each SR capsule contains: Itopride HCl sustained release pellets containing Itopride HCl….....150mg
	Diary No. Date of R & I & fee	Dy. No. 489 dated 20-12-2010, Rs. 8,000/- challan dated 22-11-2010 (Photocopy), Dy. No. 25860 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955336 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Antiemetic & antinauseant
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Ipride SR 150mg Capsule of M/s Wilshire Lahore. Registration No. 060430
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Provide evidence of applied formulation in reference regulatory authorities as adopted by Registration Board in its 275th meeting. • Firm has provided certificate of analysis for Itopride HCl SR pellets 60% from Vision Pharmaceuticals, Islamabad. • The firm to submit stability study data of 03 batches and GMP certificate of pellets manufacturer if availability of the applied formulation is established/confirmed. • The product is non-pharmacopoeial. • Firm has provided undertaken that the product (Guide SR capsule) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Deferred for:	

	• **Evidence of approval of applied formulation in reference regulatory authorities which were adopted/declared by Registration Board in its 275th meeting.** • **Submission of stability study data of three (03) batches of pellets, CoA and GMP certificate of pellets manufacturer.** • **Submission of applicable fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 for pellets source fixation.**	
613.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	KOMIN 50mg tablet
	Composition	Each tablet contains: Clomiphene Citrate…….....50mg
	Diary No. Date of R & I & fee	Dy. No. 5015 dated 06-06-2012, Rs. 8,000/- challan dated 05-06-2012 (Challn Photocopy dated 05-06-2012), Dy. No. 25849 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955335 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Ovulation stimulant
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CLOMID® 50mg tablet (Sanofi) US FDA approved
	Me-too status	Fensipro 50mg tablet of M/s Evolution pharmaceuticals Islamabad. Registration No. 101601
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Firm has provided undertaken that the product (Komin tablet 50mg) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
614.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	PERKOSET tablet
	Composition	Each tablet contains: Oxycodone (As hydrochloride) ….....10mg Paracetamol……650mg
	Diary No. Date of R & I & fee	Dy. No. 1249 dated 11-01-2011, Rs. 8,000/- challan dated 14-12-2010 (Photocopy), Dy. No. 25868 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955344 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Opioid analgesic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	(USFDA approved) Percocet (Oxycodone HCl 10 mg, Acetaminophen 325 mg) of Endo pharmaceuticals.
	Me-too status	Couldn't be confirmed
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (Psychotropic) section available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Revise label claim as per reference product as: Each tablet contains: Oxycodone hydrochloride….10mg Acetominophen……325mg • Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Firm has provided undertaken that the product (Perkoset tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
615.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	PERKOSET Syrup
	Composition	Each 5ml contains: Oxycodone (As hydrochloride) ….....5mg Paracetamol……325mg
	Diary No. Date of R & I & fee	Dy. No. 1250 dated 11-01-2011, Rs. 8,000/- challan dated 14-12-2010 (Photocopy), Dy. No. 25867 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955343 dated 13-11-2019 (Original), "Duplicate dossier,-R & I verified"
	Pharmacological Group	Opioid analgesic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Could not be confirmed
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid/syrup section (Psychotropic) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022.

		• Revise label claim as per reference product: Each 5ml contains: Oxycodone hydrochloride ….....5mg Paracetamol……325mg • Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer or else submit application on Form 5D and stability study data as per guidelines of 293rd meeting of Registration Board along with submission of applicable fee. • The product is non-pharmacopoeial. • Firm has provided undertaken that the product (Perkoset syrup) has never been discussed or deferred in any meeting and that given information are true. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability studies data as per checklist approved by RegistrationBoard in its 293rd meeting along with Form 5D declairng label claim as per reference product and differential fee.** • **Submission of fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
616.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	BONE-D tablet
	Composition	Each film-coated tablet contains: Alendronate Sodium ….....91.37mg Cholecalciferol……5600IU
	Diary No. Date of R & I & fee	Dy. No. 5635 dated 23-05-2011, Rs. 8,000/- Challan dated 15-05-2011 (Photocopy), Dy. No. 25848 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955323 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	vitamins
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	US FDA approved
	Me-too status	Fosval-D Tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 101597
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022.

		• Firm revised label claim as per reference product: Each tablet contains: Alendronate (as Sodium trihydrate) ….....70mg Cholecalciferol……5600IU (140 mcg) and submitted fee of Rs: 30,000/- vide online deposit slip No.5818095432. • Firm has provided undertaken that the product (Bone-D tablet) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved with revised label claim as: **Each tablet contains:** **Alendronate (as Sodium trihydrate) ….....70mg** **Cholecalciferol……5600IU (140 mcg)** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
617.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	DE-DROP SYRUP
	Composition	Each 5ml contains: Cholecalciferol……1000IU
	Diary No. Date of R & I & fee	Dy. No. 5632 dated 23-05-2011, Rs. 8,000/- Challan dated 16-05-2011 (Photocopy), Dy. No. 25855 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955325 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	30ml, 60ml & 120ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Oral liquid Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Provide evidence of applied formulation in reference regulatory authorities as adopted by Registration Board in its 275th meeting. • Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer. • The product is non-pharmacopoeial. • Firm has provided undertaken that the product (D-drop Syrup) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

	• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
618.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	VISKO Cream
	Composition	Each gram contains: Fluocinolone acetonide……0.25mg
	Diary No. Date of R & I & fee	Dy. No. 1243 dated 11-01-2011, Rs. 8,000/- Challan (Photocopy), Dy. No. 25869 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955347 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-inflammatory and antipruritic drugs
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	SYNALAR® (fluocinolone acetonide) Cream 0.025%s (fluocinolone acetonide 0.25 mg/g) (US FDA approved)
	Me-too status	Fucinol Cream of M/s Jaens Pharmaceutical Industries, Lahore. Registration No. 091857
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Ointment/cream Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • As per panel inspection for renewal of DML, "Three dispensing areas were developed where dispensing hoods were installed, on each for dispensing of general, psychotropic and steroidal materials". • Firm has provided undertaken that the product (Visko cream) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
619.	Name and address of manufacturer/ Applicant	M/s Xenon Pharmaceuticals (Pvt.) Ltd. 9.5-Km, Sheikhupura road, Lahore.
	Brand Name + Dosage Form + Strength	VISKO PLUS Cream
	Composition	Each gram contains: Fluocinolone acetonide……0.25mg Hydroquinone…….40mg Tretinoin…….0.05mg
	Diary No. Date of R & I & fee	Dy. No. 1247 dated 11-01-2011, Rs. 8,000/- Challan dated 14-12-2010 (Photocopy), Dy. No. 25870 dated 03-12-2019 Differential fee Rs. 12,000/- vide challan No.1955348 dated 13-11-2019 (Original), "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-inflammatory and antipruritic drugs
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	15gm, 30gm, As per SRO

	Approval status of product in Reference Regulatory Authorities	TRI-LUMA® (fluocinolone acetonide, hydroquinone, and tretinoin) cream, 0.01%/4%/0.05%. Each gram of TRI-LUMA Cream contains 0.1mg of fluocinolone acetonide, 40 mg of hydroquinone, and 0.5 mg of tretinoin. (US FDA approved)
	Me-too status	Troika Cream (Hydroquinone: 40mg (4% w/w); Tretinoin: 0.5mg (0.05% w/w); Fluocinolone acetonide: 0.1mg (0.01% w/w) of M/s ARP (Pvt) Ltd. National Industrial Zone, Rawat Islamabad. Registration No. 099219
	GMP status	Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022 and recommended renewal of DML.
	Remarks of the Evaluator (PEC-XVII)	• Ointment/cream Section (General) available as per Panel inspection for renewal of DML and regularization of sections conducted on 11-02-2022. • Firm revised label claim as per reference productd as: Each gram contains: Fluocinolone acetonide……0.01% Hydroquinone…….4% Tretinoin…….0.5%, but has not submitted the requisite fee. • The product is non-pharmacopoeial. • As per panel inspection for renewal of DML, "Three dispensing areas were developed where dispensing hoods were installed, on each for dispensing of general, psychotropic and steroidal materials". • Firm has provided undertaken that the product (Visko plus cream) has never been discussed or deferred in any meeting and that given information are true.
	Decision: Approved with Innovator's specifications & revised label claim as: **Each gram contains:** **Fluocinolone acetonide……0.01%** **Hydroquinone…….4%** **Tretinoin…….0.5%.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of Fluocinolone acetonide quantitiy from 0.25mg/gm to 0.01% in line with reference product), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
620.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	ES-PRAM 10mg tablet
	Composition	Each tablet contains: Escitalopram…....10mg
	Diary No. Date of R & I & fee	Dy. No.5904 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25155 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981955 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	antidepressant
	Type of Form	Form 5

	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lexapro® (USFDA approved with boxed warning) WARNING: SUICIDAL THOUGHTS AND BEHAVIORS
	Me-too status	Citypram tablet 10mg of M/s City pharmaceuticals, Karachi. Registration No. 103000
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised label claim as per reference product as: Each film-coated tablet contains: Escitalopram (as oxalate) …...10mg • Firm revised finished drug product specifications as per official monograph (USP). • For above revisions, the firm submitted fee of Rs: 30,000/- vide online deposit slip No.20675485926 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications and revised label claim as; **Each film-coated tablet contains:** **Escitalopram (as oxalate) …...10mg** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
621.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	ES-PRAM 20mg tablet
	Composition	Each tablet contains: Escitalopram…….....20mg
	Diary No. Date of R & I & fee	Dy. No.5905 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25156 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981953 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	antidepressant
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lexapro® (USFDA approved with boxed warning) WARNING: SUICIDAL THOUGHTS AND BEHAVIORS
	Me-too status	Citypram tablet 20mg of M/s City pharmaceuticals, Karachi. Registration No. 103001
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised label claim as per reference product as: Each film-coated tablet contains: Escitalopram (as oxalate) …...20mg • Firm revised finished drug product specifications as

		per official monograph (USP). • For above revisions, the firm submitted fee of Rs: 30,000/- vide online depost slip No.66431950814 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications and revised label claim as; **Each film-coated tablet contains:** **Escitalopram (as oxalate) …...20mg** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
622.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	FLAMIN 20mg tablet
	Composition	Each tablet contains: Piroxicam beta cyclodextrin…20mg
	Diary No. Date of R & I & fee	Dy. No. 5903 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25158 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981952 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-inflammatory And Anti-Rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BREXIN 20 mg tablets (Piroxicam 20 mg in the form of Piroxicam-beta cyclodextrin (complex) 191.2 mg, AIFA approved.
	Me-too status	Woxicam 20mg Tablet of M/s Warafana Pharmaceuticals, Kahuta Road, Islamabad. Registration No. 072300
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised label claim as per reference product as: Each tablet contains: Piroxicam (as Beta cyclodextrin) …...20mg • The product is non-pharmacopoeial. • For above revision, the firm submitted fee of Rs: 30,000/- vide online deposit slip No.3648146506 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications and revised label claim as; **Each tablet contains:** **Piroxicam (as Beta cyclodextrin) …...20mg** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
623.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	PERCIN 16mg tablet
	Composition	Each tablet contains:

		Betahistine Dihydrochloride…16mg
	Diary No. Date of R & I & fee	Dy. No. 5919 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25147 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981967 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Histamine analogue
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (uncoated tablet)
	Me-too status	Biglac Tablet 16mgof M/s Welmark Pharmaceuticals, Hattar. Registration No. 103072
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised manufacturing outlines as per label claim for uncoated tablet as initially coating process was mentioned in manufacturing outlines. • Firm revised pharmacological group as Antivertigo preparations. • For above revisons, the firm submitted fee of Rs: 7500/- vide online deposlit slip No. 658318062859 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
624.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	MELAMET tablet
	Composition	Each tablet contains: Artemether…….40mg Lumefantrine……..240mg
	Diary No. Date of R & I & fee	Dy. No.5890 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25161 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981951 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	antimalarial
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified drug
	Me-too status	Winterm 40mg/240mg tablet of M/s Winthrox laboratories, Karachi. Registration No. 100493
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.

	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised manufacturing outlines as per label claim that is for un-coated tablet instead of coated tablet. • Firm revised finished drug product specifications as per official monograph (International pharmacopoeia). • For above revisions, the firm submitted fee of Rs: 7500/- vide online deposit slip No.33837686993 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with International Pharmacopoeia specifications. • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
625.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	SPORAL 100mg capsule
	Composition	Each capsule contains: Itraconazole…..…100mg
	Diary No. Date of R & I & fee	Dy. No.5940 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25148 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981968 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Systemic antifungals
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SPORANOX® (Itraconazole 100mg) Capsules (USFDA approved)
	Me-too status	Winterm 40mg/240mg tablet of M/s Winthrox laboratories, Karachi. Registration No. 100493
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised label claim as: Each capsule contains: Itraconazole (as IR pellets) …. 100mg • Firm specified the source/vendor of "Itraconazole IR pellets 22.0% as M/s Vision Pharmaceuticals, Islamabad. • Firm has provided GMP certificate of pellets manufacturer/supplier (M/s Vision Pharmaceuticals, Islamabad) that is valid till 13-06-2024. • Firm has provided DML No. 000806 copy (Semi-basic manufacture) of M/s Vision pharmaceuticals, Islamabad.

		• Firm has provided approval letter of Itraconazole IR pellets, grnated to M/s Vision pharmaceuticals, Islamabad. • Firm provided CoA of "Itraconazole IR pellets 22.0%. • Firm has submitted real-time stability data sheets conducted at 30 ^{0}C ± 2ºC and 65%RH ± 5%RH of three batches for 36 months and accelerated stability data sheets conducted at 40 ^{0}C ± 2 ºC and 75%RH ± 5%RH of three batches for 06 months with testing points as 0, 3, 6, 9, 12, 18, 24 & 36 months (for Long term stability studies) and 0, 3 & 6 months (for Accelerated Stability Conditions). • Firm revised finished drug product specifications as per official monograph (USP). • For above revisions, the firm submitted fee of Rs: 7500/- vide online depost slip No. 635393498 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • The firm shall submit differential fee of Rs: 22500/- for label claim revision and pellets source fixation.
	Decision: Approved with USP specifications and revised label claim as: **Each capsule contains:** **Itraconazole (as IR pellets) …. 100mg** • **The firm shall submit differential fee of Rs: 22,500/- for label claim revision and pellets source fixation (Vision pharmaceutical, Islamabad) as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
626.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	F-CON 200mg capsule
	Composition	Each capsule contains: Fluconazole…..…200mg
	Diary No. Date of R & I & fee	Dy. No.5942 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25157 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981954 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Antifungals
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Trinaz Capsule 200mg of M/s Trillium pharmaceuticals, Faisalabad. Registration No. 097600
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revied finished drug product specifications as

		per official monograph (BP). • For above revision, the firm submitted fee of Rs: 7500/- vide online deposit slip No.898456744 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
627.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	BEBATE Lotion (0.05% w/v)
	Composition	Each ml contains: Betamethasone Dipropionate……..0.05% w/v
	Diary No. Date of R & I & fee	Dy. No. 5989 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25149 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981965 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	25ml/bottle, As per SRO
	Approval status of product in Reference Regulatory Authorities	DIPROSONE® (US FDA approved) Each gram of DIPROSONE Lotion 0.05% w/w contains: 0.643 mg Betamethasone Dipropionate, USP (equivalent to 0.5 mg betamethasone)
	Me-too status	Valisone 0.05% Lotion (Each ml contains: Betamethasone dipropionate eq to betamethasone: 0.5mg (0.05% w/v) of M/s Crystolite pharmaceuticals, Islamabad. Registration No. 077652
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• External liquid preparation section (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) dated 27-04-2017. • Firm revised label claim as per reference product as: Each ml contains: Betamethasone (as dipropionate) …….0.5mg (0.05% w/v) • Firm has External liquid preparation section (General) as evidence of availability of required manufacturing facility for applied formulation. • Firm has separate dispensing facility for steroidal materials as mentioned in DML renewal inspection report dated 16-06-2021 as "The firm provided raw material store with de-dusting area, one sampling booth and two dispensing booths with controlled temperature, fitted with UV light and HEPA filters. The firm has provided segregated dispensing hood for steroidal and general products". • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-

		2021 & 13-07-2021.
	Decision: Deferred for: • **Evidence of approval of requiste manufacturing facilitiy by Licensing Division.** • **Submission of fee Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 since the firm revised label claim as:** **Each ml contains:** **Betamethasone (as dipropionate) …….0.5mg (0.05% w/v)**	
628.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	BEBATE Cream (0.05% w/w)
	Composition	Each gram contains: Betamethasone Dipropionate……..0.05% w/w
	Diary No. Date of R & I & fee	Dy. No. 5973 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25151 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981964 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10gm, 15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	(US FDA approved)
	Me-too status	Valisone 0.05% cream (w/w) of M/s Crystolite pharmaceuticals, Islamabad. Registration No. 077635
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised label claim as per reference product as: Each gram contains: Betamethasone (as dipropionate) …….0.5mg (0.05% w/w). • Firm has separate dispensing facility for steroidal materials as mentioned in DML renewal inspection report dated 16-06-2021 as "The firm provided raw material store with de-dusting area, one sampling booth and two dispensing booths with controlled temperature, fitted with UV light and HEPA filters. The firm has provided segregated dispensing hood for steroidal and general products". • Fimr revised finished drug product specifications as per official monograph (USP). • For above revisions, firm submitted fee of Rs: 30,000/- vide online deposit slip No.73829610980 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications and revised label claim as: **Each gram contains:** **Betamethasone (as dipropionate) …….0.5mg (0.05% w/w).**	

	• **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
629.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	OPTEF Cream (1 % w/w)
	Composition	Each gram contains: Hydrocortisone……..10mg (1% w/w)
	Diary No. Date of R & I & fee	Dy. No.5961 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25160 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981958 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	5gm, 10gm, 20gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Arsocortison Cream 1% (10mg/gram) of M/s Arsons pharmaceuticals, Lahore. Registration No. 086342
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm has separate dispensing facility for steroidal materials as mentioned in DML renewal inspection report dated 16-06-2021 as "The firm provided raw material store with de-dusting area, one sampling booth and two dispensing booths with controlled temperature, fitted with UV light and HEPA filters. The firm has provided segregated dispensing hood for steroidal and general products". • Fimr revised finished drug product specifications as per official monograph (USP). • For above revisions, firm submitted fee of Rs: 7500/- vide online deposit slip No.47769565527 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
630.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	OPTEF Cream (2% w/w)
	Composition	Each gram contains: Hydrocortisone……..2% w/w
	Diary No. Date of R & I & fee	Dy. No.5960 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25146 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981959 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Corticosteroids

	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	5gm, 10gm, 20gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved (0.5% w/w, 1% w/w, 2.5% w/w)
	Me-too status	Hydrocort 2.5% Cream of M/s Atco laboratories, Karachi. Registration No. 067251
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised label claim as per reference product as: Each gram contains: Hydrocortisone…….25mg (2.5%) • Firm has separate dispensing facility for steroidal materials as mentioned in DML renewal inspection report dated 16-06-2021 as "The firm provided raw material store with de-dusting area, one sampling booth and two dispensing booths with controlled temperature, fitted with UV light and HEPA filters. The firm has provided segregated dispensing hood for steroidal and general products". • Fimr revised finished drug product specifications as per official monograph (USP). • For above revisions, firm submitted fee of Rs: 30,000/- vide online deposit slip No.19776957691 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications and revised label claim as: **Each gram contains:** **Hydrocortisone…….25mg (2.5%)** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
631.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	BETAVAL Cream (0.1% w/w)
	Composition	Each gram contains: Betamethasone (as valerate) …….1mg (0.1% w/w)
	Diary No. Date of R & I & fee	Dy. No. 5972 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25152 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981963 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	5gm, 15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Berate Cream 1mg/gm (0.1%) of M/s Ciba Pharmaceuticals, Karachi. Registration No. 102890

	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm has separate dispensing facility for steroidal materials as mentioned in DML renewal inspection report dated 16-06-2021 as "The firm provided raw material store with de-dusting area, one sampling booth and two dispensing booths with controlled temperature, fitted with UV light and HEPA filters. The firm has provided segregated dispensing hood for steroidal and general products". • Fimr revised finished drug product specifications as per official monograph (USP). • For above revisions, firm submitted fee of Rs:7500/- vide online deposit slip No.4900353790 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
632.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	CLOTIZOL HC Cream
	Composition	Each gram contains: Clotrimazole……10mg (1% w/w) Hydrocortisone (as Acetate) …….10mg (1% w/w)
	Diary No. Date of R & I & fee	Dy. No. 5969 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25154 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1959901 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Corticosteroid combinations
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Canesten HC Cream (MHRA approved) Each gram of cream contains 10mg clotrimazole and 11.2mg hydrocortisone acetate (equivalent to 10mg hydrocortisone)
	Me-too status	Conic-H 1% Cream Hydrocortisone (as acetate): 10mg (1% w/w); Clotrimazole: 10mg (1% w/w) of M/s Rotex pharma, Islamabad. Registration No. 100798
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm has separate dispensing facility for steroidal materials as mentioned in DML renewal inspection report dated 16-06-2021 as "The firm provided raw material store with de-dusting area, one sampling

		booth and two dispensing booths with controlled temperature, fitted with UV light and HEPA filters. The firm has provided segregated dispensing hood for steroidal and general products". • Fimr revised finished drug product specifications as per official monograph (BP). • For above revisions, firm submitted fee of Rs: 7500/- vide online deposit slip No.617633902762 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
633.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	M-CATIN Cream
	Composition	Each gm contains: Miconazole Nitrate……20mg (2% w/w) Hydrocortisone …….10mg (1% w/w)
	Diary No. Date of R & I & fee	Dy. No. 5963 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25159 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981960 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Corticosteroid combinations
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	10gm, 15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Daktacort 2% / 1% w/w cream(Miconazole nitrate and hydrocortisone) (MHRA approved)
	Me-too status	Micona H Cream (Hydrocortisone: 10mg/gm & Miconazole Nitrate: 20mg/gm of M/s Pharmasol (Pvt) Ltd. Lahore. Registration No. 100609
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm has separate dispensing facility for steroidal materials as mentioned in DML renewal inspection report dated 16-06-2021 as "The firm provided raw material store with de-dusting area, one sampling booth and two dispensing booths with controlled temperature, fitted with UV light and HEPA filters. The firm has provided segregated dispensing hood for steroidal and general products". • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
634.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.

	Brand Name + Dosage Form + Strength	CLIMEX Cream 2% (w/w)
	Composition	Each gm contains: Clindamycin (as phosphate) ……20mg (2% w/w)
	Diary No. Date of R & I & fee	Dy. No.5971 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25153 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981962 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Gynaecological anti-infective
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	20gm, 40gm, as per SRO
	Approval status of product in Reference Regulatory Authorities	Cleocin® Clindamycin phosphate vaginal cream, USP, Pfizer (Each gram of cream contains clindamycin phosphate equivalent to 20 mg or 2.0% w/w clindamycin). (USFDA approved)
	Me-too status	Sleek-V (2% w/w) Cream of M/s Health Care pharmaceuticals, Lahore. Registration No. 102347
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • Firm revised the route of administration as "Vaginal cream", instead of "topical cream" as per reference product. • The official monograph provided is for Clindamycin phosphate vaginal cream, as per USP. • For above revisions, firm submitted fee of Rs: 7500/- vide online deposit slip No.6528789685 as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
635.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	SUNSAC Cream
	Composition	Each gm contains: Fluocinolone acetonide…….0.1mg (0.01% w/w) Hydroquinone……...40mg (4% w/w) Tretinoin……...0.5mg (0.05% w/w).
	Diary No. Date of R & I & fee	Dy. No. 5958 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy.No. 25150 dated 26-11-2019 Differential fee Rs. 12,000/- vide challan No.1981969 dated 13-11-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-acne preparations
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	15gm, 30gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	TRI-LUMA® (fluocinolone acetonide, hydroquinone, and tretinoin), cream, 0.01%/4%/0.05%.

		Each gram of TRI-LUMA Cream contains 0.1mg of fluocinolone acetonide, 40 mg of hydroquinone, and 0.5 mg of tretinoin. (US FDA approved)
	Me-too status	Troika Cream (Hydroquinone: 40mg (4% w/w); Tretinoin: 0.5mg (0.05% w/w); Fluocinolone acetonide: 0.1mg (0.01% w/w) of M/s ARP (Pvt) Ltd. National Industrial Zone, Rawat Islamabad. Registration No. 099219
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment Section (General) approval granted vide letter No. F. 1-30/84-Lic (Vol.I) (M-227) dated 24-06-2011. • The product is non-pharmacopoeial.
	Decision: Approved with Innovator's specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.**	
636.	Name and address of manufacturer/ Applicant	M/s Saffron pharmaceuticals (Pvt.) Limited, 19 Km, Sheikhupura Road, Faisalabad.
	Brand Name + Dosage Form + Strength	CAGRELOR 90mg Tablets
	Composition	Each film-coated tablet contains: - Ticagrelor……..90mg
	Diary No. Date of R & I & fee	Dy. No. 5791 dated 28-06-2012, Rs. 8,000/- dated 28-06-2012 (Fee challan copy not provided), Dy.No. 745 dated 14-03-2019 Differential fee Rs. 12,000/- vide challan No.0740777 dated 11-03-2019 (Original) "Duplicate dossier, R & I verified"
	Pharmacological Group	Platelet aggregation inhibitor excluding heparin
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	10's, 20's, 30's, As per SRO
	Approval status of product in Reference Regulatory Authorities	BRILINTA® (ticagrelor) 60mg, 90mg film-coated tablets (US FDA approved)
	Me-too status	ACS Tablet 90mg of M/s Genome pharmaceuticals, Hattar. Registration No. 098704
	GMP status	GMP certificate dated 15-10-2018 issued based on evaluation conducted on 03-10-2018.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in GMP certificate dated 15-10-2018. • Provide stability study data as per guidelines of 293rd meeting of Registration Board along with submission of applicable fee. • The firm has claimed manufacturer specifications, while the product is non-pharmacopoeial.
	Decision: Deferred for submission of stability study data as per guidelines of 293rd meeting of Registration Board within 6 months.	
637.	Name and address of manufacturer/ Applicant	Shrooq Pharmaceuticals (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	CEPONATE Cream (0.1% w/w)

	Composition	Each gram of cream contains: Methylprednisolone aceponate…….0.1% w/w
	Diary No. Date of R & I & fee	Dy.No. dated, Fee Rs: 8,000/-, Date.24-05-2010, Differential fee: Rs. 12,000 Dated 26-02-2019 vide deposit slip No. 0819099 dated 18-02-2019. "Duplicate dossier"
	Pharmacological Group	Corticosteroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	ADVANTAN methylprednisolone aceponate 1mg/g cream tube. TGA approved
	Me-too status	Solu-Pred 0.1% Cream of M/s Rotex pharma, Islamabad. Registration No. 097432
	GMP status	Panel inspection for renewal of DML conducted on 26-10-2021 and 29-10-2021 and recommended renewal of DML of the firm.
	Remarks of the Evaluator	• Cream/Ointment Section (Steroidal) mentioned in GMP certificate dated 21-05-2019. • Provide DRAP R & I stamped cover letter copy of initial submission of application in the year 2010. • Verification of R & I record need to be verified. • The label claim has been revised as: Each gram of cream contains: Methylprednisolone aceponate…….0.1% w/w Since, in the composition mentioned in master formulation and differential fee R & I cover letter. as Each gram of cream contains: Methylprednisolone (As aceponate) ….0.1% w/w. • For above revision, the firm submitted fee of Rs: 7500/- vide online deposit slip No.17979271100. The firm to submit differential fee of Rs: 22,500/- for label claim revision, as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • The firm has claimed manufacturer specifications, while the product is non-pharmacopoeial.
	Decision: Deferred for following points: • **Submission of R&I receiving from DRAP for initial submission of registration application.** • **Submission of differential fee Rs: 22,500/- for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
638.	Name and address of manufacturer/ Applicant	Shrooq Pharmaceuticals (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.
	Brand Name + Dosage Form + Strength	CALCIPO Ointment (0.005% w/w)
	Composition	Each gram of ointment contains: Calcipotriol (as monohydrate) …….50mcg
	Diary No. Date of R & I & fee	Dy.No.7300 dated 30-07-2010, Fee Rs: 8,000/-, Date.30-07-2010 (Challan photocopy), Differential fee: Rs. 12,000 Dated 26-02-2019 vide deposit slip No. 0819096 dated 18-02-2019. "Duplicate dossier, R & I verified"

	Pharmacological Group	Corticosteroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	Each gram of ointment contains 0.05 mg (is equal to 50 micrograms) of calcipotriol., MHRA approved.
	Me-too status	Evonex 0.005% (0.05mg/gm) Ointment of M/s Evolution pharmaceuticals, Islamabad. Registration No. 101641
	GMP status	Panel inspection for renewal of DML conducted on 26-10-2021 and 29-10-2021 and recommended renewal of DML of the firm.
	Remarks of the Evaluator	• Cream/Ointment Section (Steroidal) mentioned in GMP certificate dated 21-05-2019. • Firm revised finished drug product specifications as per official monograph (BP). • Firm revised pharmacological group as "antipsoriatics for topical use". • Firm submitted fee of Rs: 7500/- vide online deposit slip No. 4791289939 for above revisions as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.l
	Decision: Approved with BP specifications. Registration Board further decided to verify fee challans (initial fee challan only) as per decision of 285th meeting.	
639.	Name and address of manufacturer/ Applicant	M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	SYNPRID 25mg Tablets
	Composition	Each tablet contains: - Levosulpiride ……..25mg
	Diary No. Date of R & I & fee	Dy.No.899-R&I dated 01-06-2011 Dy No.1238-DDC(R-III) dated 1-06-2011, Rs.8000/- dated 30-05-2011 (original) Dy.No.28613(R&I) DRAP dated 30-12-2019, Differential fee, Rs. 12,000/- dated 30-12-2019 vide deposit slip No.0822594 dated 26-12-2019. (original) "Original dossier"
	Pharmacological Group	Anti-dopaminergic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg, 50mg, 100mg tablets, (AIFA Italy approved).
	Me-too status	Arrser 25mg tablet of M/s Arreta pharmaceutical Rawalpindi. Registration No.100676
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • In the master formula and manufacturing outlines, coating materials and coating process is mentioned. While the label claim is of un-coated tablet. Please clarify and revise master formulation and

		manufacturing outlines accordingly. • Revise pharmacological group as "antipsychotics, benzamides". • The product is non-pharmacopoeial. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications. • **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, manufacturing outlines, pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Revised master formulation and manufacturing outlines as per applied label claim/composition which is of "uncoated tablet".**	
640.	Name and address of manufacturer/ Applicant	M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	SYNPRID 50mg Tablets
	Composition	Each tablet contains: - Levosulpiride ……..50mg
	Diary No. Date of R & I & fee	Dy.No.900-R&I dated 01-06-2011 Dy No.1237-DDC(R-III) dated 1-06-2011, Rs.8000/- dated 30-05-2011 (original) Dy.No.28614(R&I) DRAP dated 30-12-2019, Differential fee, Rs. 12,000/- dated 30-12-2019 vide deposit slip No.0822583 dated 26-12-2019. (original) "Original dossier"
	Pharmacological Group	Anti-dopaminergic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg, 50mg, 100mg tablets, (AIFA Italy approved).
	Me-too status	Arrser 50mg tablet of M/s Arreta pharmaceutical Rawalpindi. Registration No.100665
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • In the master formula and manufacturing outlines, coating materials and coating process is mentioned. While the label claim is of un-coated tablet. Please clarify and revise master formulation and manufacturing outlines accordingly. • Revise pharmacological group as "antipsychotics, benzamides". • The product is non-pharmacopoeial. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications.	

	Registration letter shall be issued upon submission of following: • **Latest GMP inspection report conducted within last three years alongwith revised master formulation and manufacturing outlines as per applied label claim/composition which is of "uncoated tablet".** • **Fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, manufacturing outlines, pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
641.	Name and address of manufacturer/ Applicant	M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	SYNPRID 100mg Tablets
	Composition	Each tablet contains: - Levosulpiride ……..100mg
	Diary No. Date of R & I & fee	Dy.No.898-R&I dated 01-06-2011 Dy No.1239-DDC(R-III) dated 1-06-2011, Rs.8000/- dated 30-05-2011 (original) Dy.No.31890(R&I) DRAP dated 29-01-2020, Differential fee, Rs. 12,000/- dated 29-01-2020 vide deposit slip No.0822598 dated 24-01-2020. (original) "Original dossier"
	Pharmacological Group	Anti-dopaminergic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg, 50mg, 100mg tablets, (AIFA Italy approved).
	Me-too status	Arrser 100mg tablet of M/s Arreta pharmaceutical Rawalpindi. Registration No.100666
	GMP status	Not provided
	Remarks of the Evaluator(PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • In the master formula and manufacturing outlines, coating materials and coating process is mentioned. While the label claim is of un-coated tablet. Please clarify and revise master formulation and manufacturing outlines accordingly. • Revise pharmacological group as "antipsychotics, benzamides". • The product is non-pharmacopoeial. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications. **Registration letter shall be issued upon submission of following:** • **Latest GMP inspection report conducted within last three years alongwith revised master formulation and manufacturing outlines as per applied label claim/composition which is of "uncoated tablet".** • **Fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, manufacturing outlines, pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

642.	Name and address of manufacturer/ Applicant	M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	DICLO-S SR 100mg capsule
	Composition	Each capsule contains: - Diclofenac Sodium ……..100mg
	Diary No. Date of R & I & fee	Dy.No.883-R&I dated 01-06-2011 Dy No.1256-DDC(R-III) dated 1-06-2011, Rs.8000/- dated 30-05-2011 (original) Dy.No.31889(R&I) DRAP dated 29-01-2020, Differential fee, Rs. 12,000/- dated 29-01-2020 vide deposit slip No.0822584 dated 24-01-2020. (original) "Original dossier"
	Pharmacological Group	Phenyl acetic acid, anti-rheumatic, analgesic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rhumalgan XL100 mg Modified-Release Capsules (MHRA Approved)
	Me-too status	Volden Forte SR 100mg Capsule of M/s Rotex pharma, Islamabad. Registration No. 100882
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • The composition mentioned in master formulation is of enteric coated pellets, while the product applied is sustained release. Please clarify and revise/provide label claim and master formulation accordingly. • Provide source of pellets, CoA, stability study data of three batches and GMP certificates of pellets manufacturer/supplier. • Revise finished drug product specifications as per official monograph (BP). • The product name mentioned in differential fee challan and cover letter as Diclocin-SR 100mg capsule. Please clarify? • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications and revised label claim as: **Each Sustained Release capsule contains:** **Diclofenac sodium (as Diclofenac sodium SR Pellets) .....100 mg** **Rregistration letter shall be issued upon submission of latest GMP inspection report conducted within last three years** • **Revised master formulation as per approved label claim for sustained release capsules.** • **Sustained released pellets source, CoA, stability study data of three batches of pellets and GMP certificate of pellets manufacturer.**	

	• **The firm shall submit applicable fee for pellets source approval/fixation as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.**	
643.	Name and address of manufacturer/ Applicant	M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	ORAZOLE Capsule
	Composition	Each capsule contains: - Omeprazole …….20mg Sodium bicarbonate……1100mg
	Diary No. Date of R & I & fee	Dy.No.880-R&I dated 01-06-2011 Dy No.1253-DDC(R-III) dated 1-06-2011, Rs.8000/- dated 30-05-2011 (original) Dy.No.31886(R&I) DRAP dated 29-01-2020, Differential fee, Rs. 12,000/- dated 29-01-2020 vide deposit slip No.0822597 dated 24-01-2020. (original) "Original dossier"
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (20 mg Omeprazole and 1,100 mg Sodium bicarbonate) capsules (USFDA Approved)
	Me-too status	Ozimed Capsule 20/1100mg of M/s Welmed pharmaceuticals, Swabi. Registration No. 102785
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • In the composition/master formulation, enteric coated pellets of omeprazole are mentioned. please clarify and revise master formulation and manufacturing outlines as per label claim. • In differential fee cover letter and fee challan, the product name given as "Carbizole capsule". Please clarify? • The product is non-pharmacopoeial. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications. Registration letter shall be issued upon submission of following: • **Revised master formulation and manufacturing outlines as per label claim.** • **Latest GMP inspection report conducted within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
644.	Name and address of manufacturer/ Applicant	M/s Medisynth Pharmaceuticals, Plot No.55, Street No.S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	ORAZOLE Capsule
	Composition	Each capsule contains: - Omeprazole …….40mg Sodium bicarbonate……1100mg
	Diary No. Date of R & I & fee	Dy.No.881-R&I dated 01-06-2011

		Dy No.1254-DDC(R-III) dated 1-06-2011, Rs.8000/- dated 30-05-2011 (original) Dy.No.31886(R&I) DRAP dated 29-01-2020, Differential fee, Rs. 12,000/- dated 29-01-2020 vide deposit slip No.0822595 dated 24-01-2020. (original) "Original dossier"
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (40 mg Omeprazole and 1,100 mg Sodium bicarbonate) capsules (USFDA Approved)
	Me-too status	Ozimed Capsule 40/1100mg of M/s Welmed pharmaceuticals, Swabi. Registration No. 102786
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • In the composition/master formulation, enteric coated pellets of omeprazole are mentioned. please clarify and revise master formulation and manufacturing outlines as per label claim. • The product is non-pharmacopoeial. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with Innovator's specifications. Registration letter shall be issued upon submission of following: • **Revised master formulation and manufacturing outlines as per label claim.** • **Latest GMP inspection report conducted within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
645.	Name and address of manufacturer/ Applicant	M/s Caraway Pharmaceuticals, Plot No.12, Street No. N-3, National Industrial Zone (RCCI), Rawat.
	Brand Name + Dosage Form + Strength	INAPAR 30mg tablet
	Composition	Each film-coated tablet contains: Cinacalcet (as hydrochloride) ……30mg
	Diary No. Date of R & I & fee	Dy.No.8413-R&I dated 15-08-2012 Dy.No.2324(R&I) DRAP dated 11-05-2017, Differential fee, Rs. 12,000/- dated 11-05-2017 vide deposit slip No.0577870 dated 11-05-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	calcimimetics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	SENSIPAR® (cinacalcet) 30mg, 60mg & 90mg film-coated tablets (USFDA Approved)
	Me-too status	Mimcipar 30mg Tablets of M/s Genome pharmaceuticals, Hattar. Registration No. 082301
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Challan of initial fee submission not provided.

		• Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • The product is non-pharmacopoeial. • Provide stability study data as per guidelines of 293rd meeting of Drug Registration Board. • The label claim has been revised as: Each film-coated tablet contains: Cinacalcet (as hydrochloride) ……30mg Since, in the cover letter of initial submission, the composition mentioned as "Cinacalcet hydrochloride….30mg • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Submission of stability study data as per guidelines of 293rd meeting of Drug Registration Board.** • **Latest GMP inspection report conducted within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
646.	Name and address of manufacturer/ Applicant	M/s Caraway Pharmaceuticals, Plot No.12, Street No. N-3, National Industrial Zone (RCCI), Rawat.
	Brand Name + Dosage Form + Strength	INAPAR 60mg tablet
	Composition	Each film-coated tablet contains: Cinacalcet (as hydrochloride) ……60mg
	Diary No. Date of R & I & fee	Dy.No.8414-R&I dated 15-08-2012 Dy.No.2324(R&I) DRAP dated 11-05-2017, Differential fee, Rs. 12,000/- dated 11-05-2017 vide deposit slip No.0577871 dated 11-05-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	calcimimetics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	SENSIPAR® (cinacalcet) 30mg, 60mg & 90mg film-coated tablets (USFDA Approved)
	Me-too status	Mimcipar 60mg Tablets of M/s Genome pharmaceuticals, Hattar. Registration No. 082302
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Challan of initial fee submission not provided. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • The product is non-pharmacopoeial. • Provide stability study data as per guidelines of 293rd meeting of Drug Registration Board. • In the cover letter of initial submission, the

		composition mentioned as "Cinacalcet hydrochloride….60mg • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Submission of stability study data as per guidelines of 293rd meeting of Drug Registration Board.** • **Latest GMP inspection report conducted within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
647.	Name and address of manufacturer/ Applicant	M/s Medicraft Pharmaceutical (Pvt.) Ltd., 126-B, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	LUMART (Dispersible) Tablet
	Composition	Each tablet contains: Artemether……20mg Lumefantrine……120mg
	Diary No. Date of R & I & fee	Dy.No.2284 DDC Reg-IV dated 06-07-2012 (original) Dy.No.546 dated 29-07-2013. Fee, Rs. 12,000/- dated 29-07-2013 vide challan No.0024741 dated 27-07-2013. (Challan photocopy) Fee Rs: 8000/- dated 16-06-2016 vide deposit slip No.0511252 dated 15-06-2016 (original). "Original dossier"
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	16's, As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified Tablet Dispersible 20mg/120mg
	Me-too status	Artecxin Dispersible Tablet of M/s Highnoon laboratories, Multan. Registration No. 062802
	GMP status	GMP inspection report dated 10-05-2022 provided, wherein the panel recommends grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as per applied formulation as: Each dispersible tablet contains: Artemether……20mg Lumefantrine….120mg • Firm revised manufacturing outlines as per applied formulation since Coating process is mentioned in manufacturing outlines while the product applied is dispersible tablet. • Tablet section (General) available as per DML renewal letter No.F.3-3/92-Lic (Vol-IV) dated 17-09-2021. • Firm submitted fee of Rs: 7500/- vide online deposit slip No. 68271839260 for above revisions, as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Firm to submit remaining fee of Rs: 22,500/- for label

		claim revision as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each dispersible tablet contains:** **Artemether…….. 20mg** **Lumefantrine…….. 120** • **Firm shall submit the fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of formulation from tablet to dispersible tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
648.	Name and address of manufacturer/ Applicant	M/s Medicraft Pharmaceutical (Pvt.) Ltd., 126-B, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	LUMART FORTE (Dispersible) Tablet
	Composition	Each tablet contains: Artemether……40mg Lumefantrine……240mg
	Diary No. Date of R & I & fee	Dy.No.2283 DDC Reg-IV dated 06-07-2012. Dy.No. 546 dated 29-07-2013. Fee, Rs. 12,000/- dated 29-07-2013 vide deposlit slip No.0024742. Fee Rs: 8000/- dated 16-06-2016 vide deposit slip No.0511253 dated 15-06-2016 (original). "Original dossier"
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	8's, As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO prequalified Tablet, Dispersible 40mg/240mg
	Me-too status	Artecxin Forte Dispersible tablet of M/s Highnoon laboratories, Lahore. Registration No. 062803
	GMP status	GMP inspection report dated 10-05-2022 provided, wherein the panel recommends grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (PEC-XVII)	• Firm revised label claim as per applied formulation as: Each dispersible tablet contains: Artemether……40mg Lumefantrine….240mg • Firm revised manufacturing outlines as per applied formulation since Coating process is mentioned in manufacturing outlines while the product applied is dispersible tablet. • Tablet section (General) available as per DML renewal letter No.F.3-3/92-Lic (Vol-IV) dated 17-09-2021. • Firm submitted fee of Rs: 7500/- vide online deposit slip No. 281791764153 for above revisions, as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Firm to submit remaining fee of Rs: 22,500/- for label claim revision as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as:	

	Each dispersible tablet contains: **Artemether…….. 40mg** **Lumefantrine…….. 240** • **Firm shall submit the fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of formulation from tablet to dispersible tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
649.	Name and address of manufacturer/ Applicant	M/s Medicraft Pharmaceutical (Pvt.) Ltd., 126-B, Industrial Estate, Hayatabad, Peshawar.
	Brand Name + Dosage Form + Strength	LUMART DS (Dispersible) Tablet
	Composition	Each tablet contains: Artemether……80mg Lumefantrine……480mg
	Diary No. Date of R & I & fee	Dy.No.2285 DDC Reg-IV dated 06-07-2012. Dy.No. 546 dated 29-07-2013. Fee, Rs. 12,000/- dated 29-07-2013. Fee Rs: 8000/- dated 16-06-2016 vide deposit slip No.0511254 dated 15-06-2016 (original). "Original dossier"
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	6's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Artecxin Plus Dispersible Tablet (80/480) of M/s Highnoon Laboratories, Lahore. Registration No. 067820
	GMP status	GMP inspection report dated 10-05-2022 provided, wherein the panel recommends grant of cGMP certificate for export purpose.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of approval of applied formulation in reference regulatory authorities as adopted by Registration Board in its 275th meeting. • Coating process is mentioned in manufacturing outlines while the product applied is dispersible tablet. • Tablet section (General) available as per DML renewal letter No.F.3-3/92-Lic (Vol-IV) dated 17-09-2021.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were declared/adopted by Registration Board in its 293rd meeting.	
650.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	XIROX 250mg capsule
	Composition	Each capsule contains: Azithromycin dihydrate…….250mg
	Diary No. Date of R & I & fee	Dy.No.733 dated 16-05-2012, Fee Rs: 8000/- dated dated 16-05-2012 vide challan dated 09-05-2012 (challan photocopy provided). Dy.No. 586 dated 20-04-2015, Differential fee dated 20-04-2015, Rs. 12,000/- vide deposit slip No.0281253 dated 17-04-2015. "Duplicate dossier, R & I verified"
	Pharmacological Group	Macrolides/ antibiotics

	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	6's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved.
	Me-too status	Mascin 250mg capsule of M/s Regal pharmaceuticals, Islamabad. Registration No. 099587
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Revise label claim as per reference product as: Each capsule contains: Azithromycin (As dihydrate) ……250mg • Provide evidence of availability of requisite testing facilities as per USP monograph, as the product testing requires Amperometric electrochemical detector. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of label claim as per reference product as;** **Each capsule contains:** **Azithromycin (as dihydrate) ……250mg** • **Evidence of availability of requisite testing facilities as per USP monograph, as the product requires amperometric electrochemical dectector.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
651.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	XIROX-D 500mg capsule
	Composition	Each capsule contains: Azithromycin dihydrate…….500mg
	Diary No. Date of R & I & fee	Dy.No. 731 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 vide challan dated 09-05-2012 (photocopy provided). Dy.No. 586 dated 20-04-2015, Differential fee dated 20-04-2015, Rs. 12,000/- vide deposit slip No.0281254 dated 17-04-2015. "Duplicate dossier, R & I verified"
	Pharmacological Group	Macrolides/ antibiotics
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	6's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed.

	Me-too status	Azmy 500mg Capsules of M/s Filix Pharmaceuticals Rawalpindi. Registration No. 077695
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Provide evidence of approval of applied formulation in reference regulatory authorities as adopted by the Registration Board in its 275th meeting. • Provide evidence of availability of requisite testing facilities as per USP monograph, as the product testing requires Amperometric electrochemical detector. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities which were adopted/declared by Registration Board in its 275th meeting.** • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.**	
652.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	FESTER 4mg Tablet
	Composition	Each tablet contains: Fesoterodine fumarate…….4mg
	Diary No. Date of R & I & fee	Dy.No. 729 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012, vide challan dated 09-05-2012 (challan photocopy provided). Dy.No. 3306 dated 02-02-2017, Differential fee dated 02-02-2017, Rs. 12,000/- vide deposit slip No.0538837 dated 13-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Muscarinic receptor antagonist with muscle relaxant and urinary anti-spasmodic properties
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TOVIAZ® (Fesoterodine fumarate) extended-release tablets 4mg, 8mg (film-coated), USFDA approved
	Me-too status	Could not be confirmed
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Provide evidence of approval of applied formulation in reference regulatory authorities as adopted by the Registration Board in its 275th meeting or else revise

		label claim as per reference product, which in the form of film-coated extended-release tablets. • The master formulation, manufacturing outlines should also be revised accordingly. • Official monograph not available. • Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer. • Resubmission of application on Form 5-D along with stability data as per guidelines of 293rd meeting of Registration board, along with submission of applicable fee. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Evidence of approval of applied formulation in reference regulatory authorities as adopted by the Registration Board in its 275th meeting or else revise label claim as per reference product, which in the form of film-coated extended-release tablets.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines of 293rd meeting of Registration Board.**	
653.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	FESTER-D 8mg Tablet
	Composition	Each tablet contains: Fesoterodine fumarate…….8mg
	Diary No. Date of R & I & fee	Dy.No. 728 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 vide challan dated 09-05-2012 (challan photocopy provided). Dy.No. 3306 dated 02-02-2017, Differential fee, Rs. 12,000/- dated 02-02-2017 vide deposit slip No.0538836 dated 13-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Muscarinic receptor antagonist with muscle relaxant and urinary anti-spasmodic properties
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2 ×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	TOVIAZ® (Fesoterodine fumarate) extended-release tablets 4mg, 8mg (film-coated), USFDA approved
	Me-too status	Could not be confirmed
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019.

		• Provide most recent/last GMP inspection report. • Provide evidence of approval of applied formulation in reference regulatory authorities as adopted by the Registration Board in its 275th meeting or else revise label claim as per reference product, which in the form of film-coated extended-release tablets. • The master formulation, manufacturing outlines should also be revised accordingly. • Official monograph not available. • Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer. • Resubmission of application on Form 5-D along with stability data as per guidelines of 293rd meeting of Registration board, along with submission of applicable fee. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Evidence of approval of applied formulation in reference regulatory authorities as adopted by the Registration Board in its 275th meeting or else revise label claim as per reference product, which in the form of film-coated extended-release tablets.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines of 293rd meeting of Registration Board.**	
654.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	ZAROFEN 80mg Tablet
	Composition	Each tablet contains: Zaltoprofen…….80mg
	Diary No. Date of R & I & fee	Dy.No. 734 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 vide challan dated 09-05-2012. Dy.No. 586 dated 20-04-2015, Differential fee, Rs. 12,000/- dated 20-04-2015 vide deposit slip No.0281255 dated 17-04-2015. "Duplicate dossier, R & I verified"
	Pharmacological Group	Non-steroidal aromatase inhibitor/ovulation stimulants
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Soleton film-coated tablet (PMDA Japan approved)
	Me-too status	Could not be confirmed
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General & Antibiotic) Sections mentioned in

		DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Revise pharmacological group as "Non-steroidal anti-inflammatory drug". • Revise label claim as per reference product as: Each film-coated tablet contains: Zaltoprofen…….80mg. The master formulation and manufacturing outlines should also be revised accordingly. • Revise finished drug product specifications as per official monograph (Japanese pharmacopoeia). • Provide evidence of drug with same formulation/composition as approved by DRAP (Me-too/generic) with proprietary name, registration number and manufacturer or else resubmit application on Form 5-D along with stability data as per guidelines of 293rd meeting of Registration board, along with submission of applicable fee. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of label claim as per reference product as:** **Each film-coated tablet contains:** **Zaltoprofen…….80mg.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data as per guidelines of 293rd meeting of Registration Board.** • **Revision of finished drug product specificaitons as per Japanese pharmacopoeia.** • **Submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and composition (from tablet to film-coated tablet) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
655.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	RICODA 5mg Tablet
	Composition	Each tablet contains: Rosuvastatin calcium…….5mg
	Diary No. Date of R & I & fee	Dy.No. 723 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 vide challan dated 09-05-2012 (Challan photocopy provided). Dy.No. 3306 dated 02-02-2017, Differential fee, Rs. 12,000/- dated 02-02-2017 vide deposit slip No.0538839 dated 13-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	HMG-CoA reductase inhibitors/Lipid lowering agent
	Type of Form	Form-5

	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Saytin Tablet 5mg of M/s Saydon pharmaceuticals, Peshawar. Registration No. 100367
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Revise label claim as per reference product as: Each film-coated tablet contains: Rosuvastatin (as calcium) …….5mg. • Revise finished drug product specifications as per official monograph (USP). • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of label claim as per reference product as:** **Each film-coated tablet contains:** **Rosuvastatin (as calcium) …….5mg.** • **Revision of finished drug product specificaitons as per official monograph (USP).** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
656.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	BONARIC 150mg Tablet
	Composition	Each tablet contains: Ibandronic acid…….150mg
	Diary No. Date of R & I & fee	Dy.No. 915 dated 07-06-2012, Fee Rs: 8000/- dated 07-06-2012 vide challan dated 29-05-2012 (Challan photocopy provided). Dy.No. 3306 dated 02-02-2017, Differential fee, Rs. 12,000/- dated 02-02-2017 vide deposit slip No.0538838 dated 13-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Bisphosphonates
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1's, As per SRO
	Approval status of product in Reference Regulatory Authorities	BONIVA (Ibandronate sodium) Tablets (USFDA approved)
	Me-too status	BONVIVA TABLET 150mg of M/s Marti Dow Ltd. Karachi. Registration No. 099494

	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Revise label claim as per reference product as: Each film-coated tablet contains: Ibandronic acid (as sodium monohydrate) …….150mg. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of label claim as per reference product as:** **Each film-coated tablet contains:** **Ibandronic acid (as sodium monohydrate) …….150mg.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
657.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	NEUROMIN 500mcg Tablet
	Composition	Each tablet contains: Mecobalamin…….500mcg
	Diary No. Date of R & I & fee	Dy.No. 726 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 vide challan dated 09-05-2012 (Challan photocopy provided). Dy.No. 3306 dated 02-02-2017, Differential fee, Rs. 12,000/- dated 02-02-2017 vide deposit slip No.0538834 dated 13-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Not provided
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Neumethecol 500mcg tablet by Hisui pharma (PMDA Japan approved)
	Me-too status	Acobmin 500mcg sugar coated tablet of M/s Cunningham Pharmaceuticals, Lahore. Registration No. 101801
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019.

		• Provide most recent/last GMP inspection report. • Revise label claim as per reference product as: Each sugar-coated tablet contains: Mecobalamin …….500mcg. • Revise finished drug product specifications as per official monograph (Japanese pharmacopoeia). • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • **Decision in 313th DRB meeting for mecobalamin 500mcg tablet "Deferred for confirmation of requirement of JP monograph regarding storage and testing of drug substance and container closure system of drug product.**
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of label claim as per reference product as:** **Each sugar-coated tablet contains:** **Mecobalamin …….500mcg.** • **Revision of finished drug product specificaitons as per Japanese pharmacopoeia.** • **Submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and composition (from tablet to sugar-coated tablet) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
658.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	UFLO-D Capsule
	Composition	Each capsule contains: Tamsulosin…….0.4mg Dutasteride…….0.5mg
	Diary No. Date of R & I & fee	Dy.No. 732 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 vide challan dated 09-05-2012 (Challan photocopy provided). Dy.No. 586 dated 20-04-2015, Differential fee, Rs. 12,000/- vide deposit slip No.0281257 dated 17-04-2015. "Duplicate dossier, R & I verified"
	Pharmacological Group	5-alpha reductase inhibitors & alpha-blockers
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	JALYN (0.5 mg Dutasteride and 0.4 mg Tamsulosin hydrochloride) capsules, USFDA approved
	Me-too status	Maxflow-D Capsule (Each capsule contains: Tamsulosin hydrochloride (extended-release pellets) eq to tamsulosin hydrochloride: 0.4mg; Dutasteride (as soft gel capsule): 0.5mg Of M/s CCL pharmaceuticals, Lahore. Registration No. 091571
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.

	Remarks of the Evaluator (PEC-XVII)	• Capsule (General & Antibiotic) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • The product approved in reference country contains Tamsulosin HCl SR pellets and soft gel capsule of Dutasteride filled in hard gelatin capsule shell. Provide the following information regarding manufacturing of the product. • Provide source of Tamsulosin Pellets, GMP certificate of pellet manufacturer, Certificate of analysis, stability study data of 3 batches according to the climatic conditions of zone IV-A and in case of imported pellets submit differential fee as well. • Provide source of Dutasteride soft gel capsule. In case of In-house manufacturing of Dutasteride soft gel capsule, provide approval of relevant section/manufacturing facility that is soft gel capsule section. In case of imported dutasteride soft gel capsule, provide the following along with the submission of differential fee: • Certificate of analysis. • Attested copy of valid Drug Sale License. • Attested copy of Valid Sole agency agreement /Authority letter. • Original Embassy attested CoPP. • Original Embassy attested GMP certificate of manufacturer. • Accelerated stability study data & Long-term Stability studies according to Zone IV-A. • Revise label claim as per reference product as: Each capsule contains: Tamsulosin hydrochloride (extended-release pellets) eq to tamsulosin hydrochloride……...0.4mg Dutasteride (as soft gel capsule) ……0.5mg • Complete method of manufactur of tamsulosin and dutasteride soft gel capsule into final dosage form. • Manufacturing facility and equipment for manufacturing. • Evidence of availability of manufacturing facility/equipment that is “capsule in capsule filling” machine. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • The drug product, FLODART™ (Dutasteride and

		Tamsulosin hydrochloride) Capsules, is a pre-printed hard-shell capsule containing one Dutasteride soft gelatin capsule (0.5 mg Dutasteride) and Tamsulosin hydrochloride pellets (containing 0.4 mg Tamsulosin hydrochloride). The pre-printed hard-shell capsules, size 00, have a brown body and an orange cap imprinted with "GS 7CZ" in black ink. The strength of each active component is identical to the commercially available AVODART®, 0.5 mg Dutasteride and FLOMAX®, 0.4 mg Tamsulosin hydrochloride. The capsules are manufactured by encapsulating two intermediate products: A Dutasteride soft gelatin capsule and Tamsulosin hydrochloride pellets, referred to as a Dutasteride Product Intermediate and Tamsulosin Hydrochloride Product Intermediate, respectively. Dutasteride Product Intermediate contains the same dose of Dutasteride as AVODART® (Dutasteride) soft gelatin capsules. The Tamsulosin Hydrochloride Product Intermediate contains the same dose as FLOMAX® (Tamsulosin hydrochloride) capsules (NDA # 20-579). The combination drug product is formulated to be bioequivalent to both commercial AVODART® and FLOMAX® dosed concomitantly. The combination capsule is intended to provide greater convenience to patients and improved compliance, relative to a regimen of two separate dosage units per day
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of label claim as per reference product as:** **Each capsule contains:** **Tamsulosin hydrochloride (extended-release pellets) eq to tamsulosin HCl…0.4mg** **Dutasteride (as soft gel capsule) ……0.5mg** • **Source of Tamsulosin Pellets, GMP certificate of pellet manufacturer, Certificate of analysis, stability study data of 3 batches according to the climatic conditions of zone IV-Al.** • **In case of In-house manufacturing of Dutasteride soft gel capsule, provide evidence of approval of requisite manufacturing facilities (Soft gel capsule Section) by Licensing Division.** • **In case of imported dutasteride soft gel capsule, provide certificate of analysis, Attested copy of valid Drug Sale License, Attested copy of Valid Sole agency agreement /Authority letter, Original Embassy attested CoPP, Original Embassy attested GMP certificate of manufacturer, Accelerated stability study data & Long-term Stability studies according to Zone IV-A conditions.** • **Complete method of manufactur of tamsulosin and dutasteride soft gel capsule into final dosage form.** • **Evidence of availability of manufacturing facility/equipment that is "capsule in capsule filling" machine.** • **Submission of fee applicable fee for pellets source fixation as per notification No.F.7-**	

	11/2012-B&A/DRAP dated 13-07-2021.	
659.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	FACID CREAM
	Composition	Each gram of cream contains: Fusidic acid…….20mg (02% w/w)
	Diary No. Date of R & I & fee	Dy.No. 737 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 dated 09-05-2012 (Challan photocopy provided). Dy.No. 3306 dated 02-02-2017, Differential fee, Rs. 12,000/- dated 02-02-2017 vide deposit slip No.0538832 dated 13-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Axxo 2% Cream of M/s Rotex pharma, Islamabad. Registration No. 100794
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment (General) & Cream/Ointment (Steroidal) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Master formulation for the applied product not provided. • Firm has claimed manufacturer specifications, however, product official monograph available in BP. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of finished drug product specificaitons as per BP monograph.** • **Submission of master formulation for the applied product.** • **Submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
660.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	FACID-H CREAM
	Composition	Each gram of cream contains: Fusidic acid…….4% Hydocortisone….1%
	Diary No. Date of R & I & fee	Dy.No. 738 dated 16-05-2012, Fee Rs: 8000/- dated 06-05-2012 vide challan dated 09-05-2012 (Challan photocopy provided).

		Dy.No. 3306 dated 02-02-2017, Differential fee, Rs. 12,000/- vide deposit slip No.0538833 dated 13-01-2017. "Duplicate dossier, R & I verified"
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	15gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (emc) Health Canada approved
	Me-too status	Axxo-H 2% Cream of M/s Rotex pharma, Islamabad. Registration No. 097434
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Cream/Ointment (General) & Cream/Ointment (Steroidal) Sections mentioned in DML renewal letter No.F.2-3/98-Lic (Vol-II) dated 17-07-2019. • Provide most recent/last GMP inspection report. • Evidence of availability of separate dispensing facility for steroidal materials. • Revise label claim as per reference product as: Each gram contains: Fusidic acid….20mg (2%) Hydrocortisone acetate……10mg (1%) • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of label claim as per reference product as:** **Each gram contains:** **Fusidic acid…….20mg (2%)** **Hydrocortisone acetate……10mg (1%)** • **Evidence of availability of separate dispensing facilities for steroidal materials.** • **Submission of fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
661.	Name and address of manufacturer/ Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	KETOFEN GEL (2.5% w/w)
	Composition	Each gram contains: Ketoprofen…….25mg
	Diary No. Date of R & I & fee	Dy.No. 719 dated 16-05-2012, Fee Rs: 8000/- dated 16-05-2012 vide challan 09-05-2012 (challan photocopy provided). Dy.No. 586 dated 20-04-2015, Differential fee, Rs. 12,000/- vide deposit slip No.0281256 dated 17-04-2015. "Duplicate dossier, R & I verified"
	Pharmacological Group	NSAID

	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30gm, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (emc) Health Canada approved
	Me-too status	Vofome Gel 2.5% of M/s E-Pharm laboratories, Karachi. Registration No. 098853
	GMP status	GMP certificate dated 20-06-2019, based on evaluation conducted on 28-02-2019.
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of relevant section approval by Licensing division, DRAP Islamabad. • Provide most recent/last GMP inspection report. • Proposed route of administration mentioned as "Oral". • Revise finished drug product specifications as per official monograph (B.P). • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Drug Manufacturing License of the firm has been suspended by the CLB in its 280th meeting dated 26-27th April 2021.** • **Revision of finished drug product specificaitons as per BP monograph.** • **Submission of revised propsed route of administration.** • **Submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
662.	Name and address of manufacturer/ Applicant	M/s Weather Folds Pharmaceuticals, Plot No.69/2, Phase-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	GO DEPRESS 20mg Tablet
	Composition	Each film-coated tablet contains: - Paroxetine (as Hydrochloride hemihydrate) …...20mg
	Diary No. Date of R & I & fee	Dy. No. 427 dated 11-06-2012, Rs. 8,000/- dated 11-06-2012 (Fee Challan copy not provided) Dy. No. dated 12-10-2015 Differential fee Rs. 12,000/- dated 12-10-2015 vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Selective serotonin-reuptake inhibitors (SSRIs)
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Depin Tablets 20mg of M/s Pharmasol, Lahore. Reg. No. 098092
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan of initial fee submission in the year 2012. • Provide DRAP R & I stamped cover letter copy of differential fee submission along with fee challan copy. • Revise label claim as per reference product as:

		Each film-coated tablet contains: Paroxetine (as hydrochloride) …….20mg • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved as per following label claim: **"Each film-coated tablet contains:** **Paroxetine (as hydrochloride) ……. 20mg"** • **Firm shall submit fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
663.	Name and address of manufacturer/ Applicant	M/s Weather Folds Pharmaceuticals, Plot No.69/2, Phase-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	AM-TEL 5mg/40mg Tablet
	Composition	Each bi-layered uncoated tablet contains: - Amlodipine Besylate eq. to Amlodipine…...5mg Telmisartan…….40mg
	Diary No. Date of R & I & fee	Dy. No. 417 dated 11-06-2012, Rs. 8,000/- dated 11-06-2012 (Fee Challan copy not provided) Dy. No. dated 12-10-2015 Differential fee Rs. 12,000/- dated 12-10-2015 vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) TWYNSTA® 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg uncoated bi-layer tablet Boehringer Ingelheim International GmbH.
	Me-too status	Tiocardis-AM Tablet 40mg/5mg of M/s Atco laboratories, Karachi. Registration No. 098764
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan of initial fee submission in the year 2012. • Provide DRAP R & I stamped cover letter copy of differential fee submission along with fee challan copy. • Firm has mentioned that the product complies innovators specifications, while official monograph available in USP. • Provide evidence of availability of bi-layered compression machine. • Provide evidence of relevant section approval by Licensing Division, DRAP Islamabad. • Firm has revised label claim as per reference product as: Each bi-layered uncoated tablet contains: - Amlodipine Besylate eq. to Amlodipine…...5mg Telmisartan…….40mg • Provide most recent/last GMP compliance inspection report.

		• Evidence of availability of bi-layered compression machine is required. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for evidence of availability of "Bi-layer tablet compression machine."	
664.	Name and address of manufacturer/ Applicant	M/s Weather Folds Pharmaceuticals, Plot No.69/2, Phase-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	D-LOX 30mg Capsule
	Composition	Each capsule contains: - Duloxetine as enteric coated pellets 17%…...30mg
	Diary No. Date of R & I & fee	Dy. No. 424 dated 11-06-2012, Rs. 8,000/- dated 11-06-2012 (Fee Challan copy not provided) Dy. No. dated 12-10-2015 Differential fee Rs. 12,000/- dated 12-10-2015 vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-depressant
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Each gastro-resistant capsule, hard contains 30 mg of duloxetine (as hydrochloride)
	Me-too status	Ducaid Capsule 30mg of M/s Medicaids (Pvt) Ltd. Karachi. Registration No. 101244
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan of initial fee submission in the year 2012. • Provide DRAP R & I stamped cover letter copy of differential fee submission along with fee challan copy. • Revise label claim as: Each hard gelatin capsule contains: Duloxetine HCl delayed release pellets (17%) eq. to doluxetine…30mg". • Provide source of pellets, CoA, stability study data of three batches and GMP certificate of pellets manufacturer/supplier. In case of imported pellets source, submit applicable fee as well. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved a sper following label claim: **"Each hard gelatin capsule contains:** **Duloxetine HCl delayed release pellets eq. to Doluxetine…….30mg."** • **Firm shall submit documents for pellets source, CoA, stability stdudy data of three batches of pellets and GMP certificate of pellets manufacturer along with fee (in case of import).** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board**	

665.	Name and address of manufacturer/ Applicant	M/s Weather Folds Pharmaceuticals, Plot No.69/2, Phase-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	D-LOX 60mg Capsule
	Composition	Each capsule contains: - Duloxetine as enteric coated pellets 17%…...60mg
	Diary No. Date of R & I & fee	Dy. No. 425 dated 11-06-2012, Rs. 8,000/- dated 11-06-2012 (Fee Challan copy not provided) Dy. No. dated 12-10-2015 Differential fee Rs. 12,000/- dated 12-10-2015 vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-depressant
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Each gastro-resistant capsule, hard contains 60 mg of duloxetine (as hydrochloride)
	Me-too status	Felice 60mg Capsules of M/s Standpharm, Pakistan, Lahore. Registration No. 100684
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan of initial fee submission in the year 2012. • Provide DRAP R & I stamped cover letter copy of differential fee submission along with fee challan copy. • Revise label claim as: Each hard gelatin capsule contains: Duloxetine HCl delayed release pellets (17%) eq. to doluxetine…60mg". • Provide source of pellets, CoA, stability study data of three batches and GMP certificate of pellets manufacturer/supplier. In case of imported pellets source, submit applicable fee as well. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved a sper following label claim: **"Each hard gelatin capsule contains:** **Duloxetine HCl delayed release pellets eq. to Doluxetine…….60mg."** • **Firm shall submit documents for pellets source, CoA, stability stdudy data of three batches of pellets and GMP certificate of pellets manufacturer along with fee (in case of import).** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board**	
666.	Name and address of manufacturer/ Applicant	M/s Winbrains Research Laboratories, Plot No.69/1, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	RAZOLE 20mg Tablet
	Composition	Each enteric coated tablet contains: - Omeprazole (as Magnesium salt) …...20mg
	Diary No. Date of R & I & fee	Dy. No. 142 dated 27-05-2011, Rs. 8,000/- dated 24-05-2011 (Fee Challan copy not provided) Differential fee Rs. dated vide challan No. dated

		"Duplicate dossier, R & I verified"
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Losec MUPS (multiple unit pellet system) 20mg AstraZeneca UK (MHRA approved) Losec 20 mg gastro-resistant tablets: Pink, oblong, biconvex, film-coated tablets, engraved with on one side and 20 mg on the other side containing enteric coated pellets.
	Me-too status	Omnat-20 Tablets of M/s Genome pharmaceuticals, Hattar. Registration No. 078431
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 not signed by firm management. • Provide fee challan of initial fee submission in the year 2011. • Provide evidence of differential fee submission. • Provide manufacturing method outlines for the product in line with innovator's manufacturing technology for multiple unit pellet system (MUPS). • The finished drug product specifications provided is for omeprazole gastro-resistant tablet, while the formulation applied is omeprazole (as magnesium salt) tablet. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for evidence of availability of requisite manufacturing facilities/technology in line with reference product for multiple unit pllets system (MUPS).	
667.	Name and address of manufacturer/ Applicant	M/s Winbrains Research Laboratories, Plot No.69/1, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	DICLO-K 50mg Tablet
	Composition	Each film coated tablet contains: - Diclofenac potassium…...50mg
	Diary No. Date of R & I & fee	Dy. No. 138 dated 27-05-2011, Rs. 8,000/- dated 24-05-2011 (Fee Challan copy not provided) Differential fee Rs. dated vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Dicloflex-P Tablet 50mg of M/s MKB pharmaceuticals Peshawar. Registration No. 102825
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence differential fee submission. • Provide most recent/last GMP compliance inspection report.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	

668.	Name and address of manufacturer/ Applicant	M/s Winbrains Research Laboratories, Plot No.69/1, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	LODEPRESS 20mg Tablet
	Composition	Each film-coated tablet contains: - Paroxetine (as Hydrochloride hemihydrate) …...20mg
	Diary No. Date of R & I & fee	Dy. No. 432 dated 11-06-2012, Rs. 8,000/- dated 11-06-2012 (Fee Challan copy not provided) Differential fee Rs. dated vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Selective serotonin re-uptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved)
	Me-too status	Depin Tablets 20mg of M/s Pharmasol, Lahore. Reg. No. 098092
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Form-5 not signed by firm management. • Provide fee challan of initial fee submission in the year 2011. • Provide evidence of differential fee submission. • Revise label claim as per reference product as: Each film-coated tablet contains: Paroxetine (as Hydrochloride) ……20mg • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved as per following label claim: **Each film-coated tablet contains:** **Paroxetine (as Hydrochloride) ……20mg** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
669.	Name and address of manufacturer/ Applicant	M/s Winbrains Research Laboratories, Plot No.69/1, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	AM-TELMA 5/40mg Tablet
	Composition	Each bi-layered uncoated tablet contains: - Amlodipine Besylate eq. to Amlodipine…...5mg Telmisartan…….40mg
	Diary No. Date of R & I & fee	Dy. No. 430 dated 11-06-2012, Rs. 8,000/- dated 11-06-2012 (Fee Challan copy not provided) Differential fee Rs. dated vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(USFDA approved) TWYNSTA® 40/5 mg, 40/10 mg, 80/5 mg, 80/10 mg uncoated bi-layer tablet Boehringer Ingelheim International GmbH.
	Me-too status	Tiocardis-AM Tablet 40mg/5mg of M/s Atco laboratories, Karachi. Registration No. 098764

	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan of initial fee submission in the year 2011. • Provide evidence of differential fee submission. • Firm has revised label claim as per reference product as: Each bi-layered uncoated tablet contains: - Amlodipine Besylate eq. to Amlodipine…...5mg Telmisartan…….40mg • Provide most recent/last GMP compliance inspection report. • Provide evidence of requisite manufacturing facilities (bi-layered compression machine) for the applied formulation. • Firm has claimed that the product complies innovators specifications, while official monograph available in USP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for following: • **Evidence of availability of "Bi-layer compression" machine along with its IQ,OQ & PQ reports.** • **Submission of fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from plain tablet bi-layered tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
670.	Name and address of manufacturer/ Applicant	M/s Winbrains Research Laboratories, Plot No.69/1, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	LOXIT 60mg Capsule
	Composition	Each capsule contains: - Duloxetine as enteric coated pellets 17%…...60mg
	Diary No. Date of R & I & fee	Dy. No. 429 dated 11-06-2012, Rs. 8,000/- dated 11-06-2012 (Fee Challan copy not provided) Differential fee Rs. dated vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-depressant
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	(MHRA approved) Each gastro-resistant capsule, hard contains 60 mg of duloxetine (as hydrochloride)
	Me-too status	Felice 60mg Capsules of M/s Standpharm, Pakistan, Lahore. Registration No. 100684
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan copy of initial fee submission in the year 2011. • Provide evidence of differential fee submission. • Revise label claim as: Each hard gelatin capsule contains: Duloxetine HCl delayed release pellets (17%) eq. to doluxetine…60mg". • Provide source of pellets, CoA, stability study data of three batches and GMP certificate of pellets manufacturer/supplier. In case of imported pellets source, submit applicable fee as well.

		• Provide most recent/last GMP compliance inspection report. • Firm has claimed that the product complies innovators specifications, while official monograph available in USP. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved as per following label claim: **"Each hard gelatin capsule contains:** **Duloxetine HCl delayed release pellets eq. to Doluxetine…60mg."** **Registration letter will be issued upon submission of following:** • **Documenst for pellets source, CoA, stability stdudy data of three batches of pellets and GMP certificate of pellets manufacturer and fee (in case of import).** • **Fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
671.	Name and address of manufacturer/ Applicant	M/s Winbrains Research Laboratories, Plot No.69/1, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	PREGBA 50mg Capsule
	Composition	Each capsule contains: - Pregabalin…...50mg
	Diary No. Date of R & I & fee	Dy. No. 131 dated 27-05-2011, Rs. 8,000/- dated 24-05-2011 (Fee Challan copy not provided) Differential fee Rs. dated vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-convulsant
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Gabler 50mg Capsule of M/s Innvotek Pharmaceuticals, Islamabad. Registration No. 102507
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan of initial fee submission in the year 2011. • Provide evidence of differential fee submission. • Firm has given innovators specifications and monograph provided from Indian pharmacopoeia. • Provide most recent/last GMP compliance inspection report.
	Decision: Approved with BP specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
672.	Name and address of manufacturer/ Applicant	M/s Winbrains Research Laboratories, Plot No.69/1, Block-B, Phase I-II, Industrial Estate, Hattar.
	Brand Name + Dosage Form + Strength	GABAPEN 300mg Capsule
	Composition	Each capsule contains: - Gabapentin…...300mg

	Diary No. Date of R & I & fee	Dy. No. 134 dated 27-05-2011, Rs. 8,000/- dated 24-05-2011 (Fee Challan copy not provided) Differential fee Rs. dated vide challan No. dated "Duplicate dossier, R & I verified"
	Pharmacological Group	Anti-convulsant
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Vegapent 300mg Capsule of M/s Vega pharmaceuticals, Lahore. Registration No. 102384
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Provide fee challan of initial fee submission in the year 2011. • Provide evidence of differential fee submission. • Provide most recent/last GMP compliance inspection report.
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
673.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	OXIFLOX 4mg TABLET
	Composition	Each film-coated tablet contains: - Moxifloxacin (As hydrochloride) …...400mg
	Diary No. Date of R & I & fee	Dy. No.1131 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577579 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Quinolones
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	5's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Oxef 400mg Tablet of M/s Parmedic laboratories, Lahore. Registration No. 100852
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise finished drug product specifications as per official monograph (USP). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	

674.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	METHLUM TABLET
	Composition	Each film-coated tablet contains: - Artemehter…...20mg Lumefantrine…….120mg
	Diary No. Date of R & I & fee	Dy. No.1097 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577584 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Synthetic anti-malarial derived from artemisinin/synthetic racemic fluorine mixture
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	16's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Prequalified by WHO
	Me-too status	Ajmetlum Tablet 20/120mg of M/s AJM pharma, Karachi. Registration No. 103049
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise label claim as per reference product as: Each tablet contains: Artemether……20mg Lumefantrine……120mg • Revise finished drug product specifications as per official monograph (International pharmacopoeia). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with International Pharmacopoeia specifications and revised label claim as: **"Each tablet contains:** **Artemether……20mg** **Lumefantrine……120mg."** • **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith f fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and composition (from film-coated tablet to core tablet) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challans as per decision of 285th meeting.**	
675.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	METHLUM-DS TABLET
	Composition	Each film-coated tablet contains: - Artemehter…...40mg Lumefantrine…….240mg
	Diary No. Date of R & I & fee	Dy. No.1095 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577587 dated 26-11-2019 (original).

		(Duplicate dossier, R & I verified)
	Pharmacological Group	Synthetic anti-malarial derived from artemisinin/synthetic racemic fluorine mixture
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	08's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Prequalified by WHO
	Me-too status	Winterm 40mg/240mg tablet of M/s Winthrox laboratories, Karachi. Registration No. 100493
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise label claim as per reference product as: Each tablet contains: Artemether……40mg Lumefantrine……240mg • Revise finished drug product specifications as per official monograph (International pharmacopoeia). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with International Pharmacopoeia specifications and revised label claim as: **Each tablet contains:** **Artemether……40mg** **Lumefantrine……240mg.** • **Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years alongwith f fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and composition (from film-coated tablet to core tablet) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
676.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TENDEC PLUS TABLET
	Composition	Each film-coated tablet contains: - Atenolol…...50mg Chlorthalidone…….12.5mg
	Diary No. Date of R & I & fee	Dy. No.1124 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577581 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Cardioselective beta-blocker/thiazide diuretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (film-coated tablet)
	Me-too status	Wnsol C Tablet 50mg/12.5mg of M/s Welmark pharmaceuticals, Hattar. Registration No. 095931
	GMP status	Not provided

	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise finished drug product specifications as per official monograph (USP). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Registration letter shall be issued upon submission of latest GMP inspection report conducted within last three years along with fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. • **Registration Board further decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
677.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	LSK-H TABLET
	Composition	Each film-coated tablet contains: - Losartan potassium…...50mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R & I & fee	Dy. No.1130 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577578 dated 26-11-2019 (original). "Duplicate dossier, R & I verified"
	Pharmacological Group	Angiotensin II receptor antagonist/thiazide diuretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (film-coated tablet)
	Me-too status	Lozarta HCT Tablet 50mg/12.5mg of M/s Lisko Pakistan, Karachi. Registration No. 094816
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise finished drug product specifications as per official monograph (USP). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Registration letter shall be issued upon submission of: • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board further decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
678.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ANTRON TABLET
	Composition	Each film-coated tablet contains: -

		Ondansetron (as hydrochloride dihydrate) …...8mg
	Diary No. Date of R & I & fee	Dy. No.1126 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577578 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Anti-emetics
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN® (ondansetron hydrochloride) 4mg & 8mg tablets Novartis pharma (US FDA approved)
	Me-too status	Ondesmed Tablet 8mg Medicraft Pharmaceuticals (Pvt) Ltd. Peshawar. Registration No. 101379
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise finished drug product specifications as per official monograph (USP). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Registration letter shall be issued upon submission of: • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
679.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TRAMADEC-SR 100mg TABLET
	Composition	Each sustained release tablet contains: - Tramadol hydrochloride…...100mg
	Diary No. Date of R & I & fee	Dy. No.1121 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577594 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Opiate analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Maneo 100 mg Prolonged-release tablets (MHRA approved)
	Me-too status	Taram-SR Tablet (Each film coated sustained release tablet contains. tramadol HCl….100mg) of Noa hemis pharmaceuticals, Karachi. Registration No. 100224
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019.

		• Revise finished drug product specifications as per official monograph (USP). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Registration letter shall be issued upon submission of: • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
680.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	OXITHRO 150mg TABLET
	Composition	Each film-coated tablet contains: - Roxithromycin…...150mg
	Diary No. Date of R & I & fee	Dy. No.1123 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577593 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Macrolide
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1×10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	ROXIMYCIN 150mg film coated tablet (TGA Approved)
	Me-too status	Roxtro Tablet 150mg of M/s Lisko Pakistan, Karachi. Registration No. 100444
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovator's specifications. Registration letter shall be issued upon submission of: • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
681.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	ASTHAMAID 5mg TABLET
	Composition	Each film-coated tablet contains: - Monteluksat (as sodium) ……5mg

	Diary No. Date of R & I & fee	Dy. No.1127 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577592 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Leukotriene receptor antagonist / anti-asthamatic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2×7's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair (4mg, 5 mg) Chewable Tablet (US FDA Approved)
	Me-too status	Dowkast 5mg chewable tablet of M/s Seatle (Pvt) Ltd. Lahore Registration No. 103296
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Provide evidence of approval of applied formulation in reference regulatory authorities as adopted by the registration board in its 275th meeting or else revise label claim as per reference product as: Each chewable tablet contains: Montelukast (as sodium) ……5mg, along with submission of revised master formulation and manufacturing outlines. • Revise finished drug product specifications as per official monograph (USP). • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications and revised label claim as: **Each chewable tablet contains:** **Montelukast (as sodium) ……5mg** **Registration letter shall be issued upon submission of:** • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from film-coated tablet to chewable tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
682.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	N-FLOX 400mg TABLET
	Composition	Each film-coated tablet contains: - Norfloxacin…...400mg
	Diary No. Date of R & I & fee	Dy. No.1096 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577580 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Quinolones
	Type of Form	Form 5
	Finished product Specification	USP specifications

	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	(US FDA approved) Noroxin 400mg of Merck Sharp & Dohme. status is discontinued with remarks **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	Me-too status	Nortic 400mg tablet of M/s Reign pharmaceuticals, Karachi. Registration No.100087
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise composition/master formulation and manufacturing outlines as per label claim since coating materials and coating process not mentioned. • The firm has claimed USP specifications, while the product was previously available in USP, is unavailable in version USP 43 NF 38 and in version USP 44 NF 39 2021, available with remarks "delete the following". • Official monograph available in BP and Japanese Pharamcopoeis. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications. Registration letter shall be issued upon submission of: • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
683.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	IPTOZ TABLET
	Composition	Each chewable tablet contains: - Iron (III) hydroxide polymaltose complex equivalent to elemental Iron…...100mg Folic acid…….0.35mg
	Diary No. Date of R & I & fee	Dy. No.1129 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577589 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	2 × 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Fogyma 100mg/0.35mg chewable tablet of M/s Theramed Pharma, Lahore. Reg.No. 101702
	GMP status	Not provided

	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Ferrum Fol 100 mg / 350 micrograms, Chewable Tablets (Iron as Iron (III)-hydroxide polymaltose complex / folic acid) Vifor France (PIL available on google) • Firm has claimed manufacturer specifications, while official monograph not available. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
684.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	YDOX 50mg TABLET
	Composition	Each film-coated tablet contains: - Doxycycline (as Hyclate) ……50mg
	Diary No. Date of R & I & fee	Dy. No.1105 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577577 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Antibiotic, tetracycline derivative
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Could not be confirmed
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Provide evidence of drug already approved by DRAP (generic/me-too) with brand name, registration number and manufacturer. • Revise composition/master formulation and manufacturing outlines as per label claim since coating materials and coating process not mentioned. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Revision of master formulation/composition and manufacturing outlines as per applied formulation as coating materials and coating process not mentioned.**	

	• **Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of master formulation and manufacturing outlines, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
685.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TRAMADEC CAPSULE
	Composition	Each capsule contains: - Tramadol hydrochloride…...50mg
	Diary No. Date of R & I & fee	Dy. No.1101 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577588 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Opiate analogue
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Hard capsule)
	Me-too status	Macmadol 50mg Capsule of M/s Searl IV solutions, Lahore. Registration No. 101674
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Capsule (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise composition/master formulation and manufacturing outlines as per label claim as the master formulation and manufacturing outlines are provided for tablet dosage form. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration letter shall be issued upon submission of: • **GMP audit report from QA & LT Division, valid within last three years.** • **Revised master formulation/composition and manufacturing outlines for applied formulation (capsule dosage form).** • **Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of master formulation and manufacturing outlines, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **Registration Board decided to verify fee challan (initial fee challan) as per decision of 285th meeting of Registration Board.**	
686.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	TECHNOVIT-C tablet
	Composition	Each film-coated tablet contains: - Thiamine mononitrate (Vit. B1) ……...15mg Riboflavin (Vit.B2) ……15mg Pyridoxine HCl (Vit.B6) …….10mg Cyanocobalamine (Vit. B12) ……10mcg Calcium Pantothenate……25mg Nicotinamide……50mg Ascorbic acid (Vit. C)…….300mg
	Diary No. Date of R & I & fee	Dy.No. dated 24-05-2011, Fee Rs: 8000/- dated 24-05-2011 (Challan photocopy dated 23-05-2011)

		Dy. No.1118 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577591 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Polybion Forte 'C' tab Thiamine mononitrate……. 15mg Riboflavin……15mg Pyridoxine HCl……. 10mg Cyanacoblamine…… 10mcg Calcium pantothenate…… 25mg Nicotinamide…… 50mg Ascorbic acid…… 300mg of M/s Martin Dow Marker Ltd. Quetta. Registration no. 001492
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Provide evidence of approval of applied formulation in reference regulatory authorities as declared/adopted by Registration Board in its 275th meeting. • The firm has provided two different DRAP R & I stamped cover letters dated 24-05-2011 & 03-06-2011 with respective fee challans for the same formulation. Needs clarification. • Revise composition/master formulation and manufacturing outlines as per label claim since coating materials and coating process not mentioned. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product composition for film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latets GMP inspection report conducted within last three years. GMP audit report from QA & LT Division, valid within last three years. • **Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**	
687.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	FIZCAL-1000 TABLET
	Composition	Each effervescent tablet contains: - Calcium Lactate …… 422mg Calcium Gluconate …… 578mg Calcium Carbonate …… 327mg Sodium Carbonate ……. 1gm Vitamin C ……. 500mg Sugar ……. 2gm Orange Flavour ……... 50mg

	Diary No. Date of R & I & fee	Dy.No. dated 24-05-2011, Fee Rs: 8000/- dated 24-05-2011 (Challan photocopy dated 23-05-2011) Dy. No.1128 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577585 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Calcium supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	CaC-1000 Effervescent Tablet (Calcium Lactate Gluconate……...1000mg (Calcium Gluconate ….578mg) (Calcium Lactate……...422mg) Vitamin C (Ascorbic Acid) …….…….500mg Calcium Carbonate ……327mg of M/s GSK OTC (Pvt) Ltd. Jamshoro. Registration No. 084642
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Tablet (General) Section mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise composition/master formulation as per label claim that is for effervescent tablet. • The firm has provided two different DRAP R & I stamped cover letters dated 24-05-2011 & 03-06-2011 with respective fee challans for the same formulation. Needs clarification. • Provide evidence of drug already approved by DRAP (generic/me-too) with brand name, registration number and manufacturer as the me-too provided has different composition than the applied formulation. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **GMP audit report from QA & LT Division, valid within last three years.** • **Revise composition/master formulation as per label claim that is for effervescent tablet.** • **Provide evidence of drug already approved by DRAP (generic/me-too) with brand name, registration number and manufacturer as the me-too provided has different composition than the applied formulation.**	
688.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	CB SOLE SOLUTION TOPICAL (0.05%)
	Composition	Each ml contains: - Clobetasol propionate…...0.5mg
	Diary No. Date of R & I & fee	Dy. No.1111 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577596 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)

	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	14's, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Gratvate 0.05% Topical Solution of M/s Greater pharma, Rawalpindi. Registration No. 097577
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Topical Lotion (General) Section & Cream/ointment (General) Section are mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise manufacturing outlines as per applied formulation since minoxidil is mentioned in manufacturing outlines. • Firm product Scalpvate liquid (topical lotion), Clobetasol propionate…0.5mg has been approved in DRB meeting 316th. Clarification from the firm is required. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Evidence of approval of requisite manufacturing facilities/section by Licensing division for topical solution preparation.** • **Revision of manufacturing outlines as per applied formulation since minoxidil is mentioned in manufacturing oultines submitted by the firm.** • **Clarification from the firm is required as the product Scalpate liquid (topical lotion) with same composition (Clobetasol propionate….0.5mg) as that of the applied product has been approved in 316th meeting of Registration Board, in the name of M/s Derma Techno Pakistan, Lahore.** • **GMP audit report from QA & LT Division, valid within last three years.**	
689.	Name and address of manufacturer/ Applicant	M/s Derma Techno Pakistan, Plot No. 528, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name + Dosage Form + Strength	CB SOLE-S LOTION
	Composition	Each ml contains: - Clobetasol propionate…...0.5mg Salicylic acid…….20mg
	Diary No. Date of R & I & fee	Dy. No.1110 dated 03-06-2011, Rs. 8,000/- dated 03-06-2011 (Fee challan copy dated 01-06-2011 provided) Dy.No.26881(R & I) dated 12-12-2019, Differential fee Rs. 12,000/- dated 12-12-2019 vide challan No.0577595 dated 26-11-2019 (original). (Duplicate dossier, R & I verified)
	Pharmacological Group	Corticosteroid / antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	20ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Clobetred-S Each ml contains: - Clobetasol ..... 0.525mg Salicylic Acid .... 20mg) of Mass pharma, Lahore.

		Registration No. 037636
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Topical Lotion (General) Section & Cream/ointment (General) Section are mentioned in letter No.F.1-51/2005-Lic (Vol-I) dated 17-07-2019. • Revise manufacturing outlines as per applied formulation since betamethasone valerate is mentioned in manufacturing outlines. • Provide evidence of approval of applied formulation in reference regulatory authorities which were declared/adopted by the Registration Board in its 275th meeting. • Provide evidence of drug already approved by DRAP (generic/me-too) with brand name, registration number and manufacturer as the me-too provided has different composition than the applied formulation. • Provide most recent/last GMP compliance inspection report. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm me-too provided has different composition than the applied formulation.** • **Evidence of approval of requisite manufacturing facilities/section by Licensing division for topicla solution preparation.** • **Revision of manufacturing outlines as per applied formulation since Betamethasone valerate is mentioned in manufacturing oultines submitted by the firm.**	

b. Deferred Cases

690.	Name and address of manufacturer/ Applicant	M/s ZAFA Pharmaceutical Laboratories (Private) Limited, L1/B Block-22 Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	TRIMEZAT Oral Suspension (24mg/5ml)
	Composition	Each 5ml contains: Trimebutine…….24mg
	Diary No. Date of R & I & fee	Dy.No. 254 dated 21-05-2011, Fee Rs: 8,000/- dated 21-05-2011 vide Challan Dated 10-05-2011 (Challan photocopy), Dy.No. 1210 dated 10-01-2019, Differential fee: Rs. 12,000 Dated 09-01-2019 vide deposit slip No. 0730282 dated 02-01-2019 (original). "Duplicate dossier, R & I verified"
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	MODULON CHILD AND INFANT 4.8 mg / ml, granulated (granules composition per 100 g

		>trimebutine: 0.7870 g) for oral suspension in vial. **ANSM** approved
	Me-too status	Tributine Suspension (trimebutine maleate). Reg. No. 031964 (tributine 0.48gm/100ml or 24mg/5ml)
	GMP status	GMP certificate dated 25-08-2022 based on evaluation conducted on 12-08-2022.
	Remarks of the Evaluator (PEC-IX)	• The me-too product contains trimebutine maleate, while the international product contains trimebutine. • The firm revised the formulation from 'powder for suspension' to 'granules for suspension'. • The firm was asked to provide complete finished product specification and testing method. However, the firm did not submit the same.
	Decision of 288th meeting of Registration Board (14-15th Feb,2019)	• Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submission of complete finished product specification and testing method including dissolution test and content uniformity test. • Submission of fee for revision of formulation. • Consideration on its turn.
	Remarks of the Evaluator (PEC-XVII)	• The firm has claimed manufacturer specifications. Official monograph not available. • Dry Powder Suspension (General) Section approved vide DML renewal letter No.F.2-11/2002-Lic (Vol-I) dated 26-05-2022. • The approval status in ANSM is either archived or repealed. • Firm provided generic/me-too evidence as Debridat Oral Suspension (Each 100ml contains: Trimebutine….0.48gm) of M/s Zafa Pharmaceutical Labs (Pvt.) Ltd. Karachi. Registration No.016064. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted/declard by Registration Board in its 275th meeting as the approval status in ANSM France is either arhived or repealed.	

Case No. 3: Registration applications for local manufacturing of (Veterinary) drugs. (Differential fee)

a; New cases:

691.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	LEVAMARS 1.5% Oral Suspension
	Composition	Each 1000ml suspension contains: Levamisole Hydrochloride……15gm Carrier Q.S to……1000ml
	Diary No. Date of R & I & fee	Form- 5, Dy. No.248 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551828 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic/dewormers
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5 litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Levami 1.5% suspension (Levamisole HCl…...1.5%) of M/s Inshal Pharma, Rawat, Islamabad. Registration No.075757 Levamit Drench (Oral Drench), Each ml contains levamisole HCl…15mg Wimitis pharmaceuticals, Lahore. RegistrationNo.078333 Levomex Drench (Oral Drench) Levamisole HCl….1.5%, Hawk Biopharma, Rawalpindi. Registration No.078391
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In response to deficiency letter No.F.1-1/2017/PEC-DRAP (AD PEC-V) dated 23rd November, 2018, you vide letter No. ZPF/Inch (PEC)/001/DRAP/2019, dated nil specified the proposed route of administration as "oral suspension", revised the master formulation by replacing the coloring agent from tartrazine yellow to Parrot green and excluded the 2% overage of Levamisole hydrochloride in master formulation. It is therefore advised to submit the requisite fee accordingly. • The finished drug product specifications such as assay and identification are given as per B.P monograph for "Levamisole oral solution", while the applied formulation is "Oral Suspension". Please clarify? • Provide most recent GMP inspection report conducted within last three years.
	Decision: Approved with BP specifications and revised label claim as: **Each 1000ml oral solution contains:** **Levamisole hydrochloride…….15gm.** **Registration letter shall be issued upon submission of following documents:** • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from suspension to solution), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
692.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.

	Brand Name + Dosage Form + Strength	LEVAMARS 15% Oral Solution
	Composition	Each 1000ml oral solution contains: Levamisole Hydrochloride……150gm
	Diary No. Date of R & I & fee	Form- 5, Dy. No.226 dated 24-05-2011 Rs.8000/- dated 23-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551819 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic/dewormers
	Type of Form	Form 5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5 litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	SB Levonex oral solution (Levamisole HCl…...15% w/v) of M/s SB Pharma Islamabad. Registration No.029630
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In initial and differential fee challans, product mentioned is "Oral suspension", while in cover letter, Form-5 and enclosures, the product mentioned is "Oral solution". • Tartrazine yellow color is mentioned in master formulation, which is not permissible. • The assay limits given as "90-110%", while as per BP Veterinary monograph for Levamisole oral solution, the limits are "92.5-107.5%. • Provide most recent GMP inspection report conducted For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration letter shall be issued upon submission of following: • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of formulation from suspension to solution), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
693.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	LEVOXINID Oral Suspension
	Composition	Each 1000ml suspension contains: Levamisole Hydrochloride……15gm Oxyclozanide…….30gm Carrier Q.S to……1000ml
	Diary No. Date of R & I & fee	Form- 5, Dy. No.380 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551833 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic/dewormers
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications

	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5 litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Alinil suspension of M/s Alina Combine Pakistan, Karachi. Registration No.025364 Getzan Drench of M/s Guyton pharmaceuticals, Lahore. Registration No.039904
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In initial fee challan, the product mentioned is "Oral solution", while in differential fee challan, Form-5 and enclosures, the product mentioned is "Oral suspension". Please clarify? • Tartrazine yellow color is mentioned in master formulation, which is not permissible. • Both APIs are added in 2% excess as overage, in master formulation. • The identification and assays methods are provided as per BP Vet individual monographs for Levamisole oral solution and oxyclozanide oral suspension. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved. Registration letter shall be issued upon submission of following: • **GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of master formulation without overage, product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
694.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	LEVOXY GOLD (Oral Solution)
	Composition	Each 1000ml solution contains: Levamisole Hydrochloride……30gm (3%) Oxyclozanide…….60gm (6%) Cobalt Sulphate……...7.64gm (0.764%) Sodium Selenite…….0.76gm (0.076%) Carrier Q.S to…….1000ml
	Diary No. Date of R & I & fee	Form- 5, Dy. No.251 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551831 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic/dewormers
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5 litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Leox DS Plus suspension Each 100ml contains: - Levamisole HCl … 03.00%. Cobalt sulphate … 0.764 % Sodium selenate …. 0.076%.

		Oxyclozanide …. 06.00%. M/s Elko organization Pvt ltd. Karachi. Registration No.031595 Helmex gold drench Each ml contains; - Levamisole hcl….30mg Oxyclozanide….60mg Cobalt sulphate…...3.34mg Sodium selenite….1.00mg Selmore pharmaceuticals, Lahore Registration No. 057005
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In response to deficiency letter No.F.1-1/2017/PEC-DRAP (AD PEC-V) dated 23rd November, 2018, you vide letter No. ZPF/Inch (PEC)/002/DRAP/2019, dated nil, specified the proposed route of administration as "oral solution", revised the master formulation by replacing the coloring agent from tartrazine yellow to Parrot green and has also revised the label claim/composition as follows: Each 1000ml solution contains: Levamisole Hydrochloride……30gm Oxyclozanide…….60gm Cobalt Sulphate……...3.34mg/ml Sodium Selenite…….1.00mg/ml • In differential fee challan, the product mentioned as "Levoxy gold oral suspension". • The finished drug product specifications claimed as per BP but could not be confirmed in BP. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 1000ml solution contains:** **Levamisole Hydrochloride……30gm** **Oxyclozanide…….60gm** **Cobalt Sulphate……...3.34mg/ml** **Sodium Selenite…….1.00mg/ml** **Registration letter shall be issued upon submission of following:** • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of quantities of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
695.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	LEVATRIC (Oral Suspension)
	Composition	Each 1000ml suspension contains: Levamisole Hydrochloride……15gm (1.5%) Triclabendazole…….50gm (5%) Carrier Q.S to……. 1000ml
	Diary No. Date of R & I & fee	Form- 5, Dy. No.249 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original)

		Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551829 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic/dewormers
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5 litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Proven drench Each ml contains: - Triclabendazole…50 mg Levamisole……. 37.50 mg Mylab (pvt) ltd. Bahawalpur Registration no.073903 Faguzol oral suspension Each ml contains: Triclabendazole…....50mg Levamisole as HCl …...37.5mg M/s. Farm aid group, Hattar Industrial Estate, Haripur. Registration No. 088024 Triclasole plus oral liquid Each 100ml contains: - Triclabendazole…5gm Levamisole……3.75gm M/s. Baariq pharmaceuticals, sunder industrial estate, Sunder raiwind road, Lahore. Registration No. 080153 Vamisol-t suspension Each 100ml contains: - Triclabendazole….5g Levamisole……3.75g M/s. Univet pharmaceuticals, Rawalpindi. Registration No. 079132
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In response to deficiency letter No.F.1-1/2017/PEC-DRAP (AD PEC-V) dated 23rd November, 2018, you vide letter No. ZPF/Inch (PEC)/007/DRAP/2019, dated nil, specified the proposed route of administration as "oral suspension", revised the master formulation by replacing the coloring agent from tartrazine yellow to Parrot green, excluded the 2% overage of APIs in master formulation and has also revised the label claim/composition as follows: Each 1000ml suspension contains: Levamisole ……37.5gm Triclabendazole……50gm • The finished drug product specifications claimed as per BP but could not be confirmed in BP.

		• For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 1000ml suspension contains:** **Levamisole ……37.5gm** **Triclabendazole……50gm** **Registration letter shall be issued upon submission of following:** • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of quantities of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
696.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ENCOL (Oral Solution)
	Composition	Each 1000ml Oral Solution contains: Enrofloxacin …...……100gm Colistin Sulphate…….50MIU Carrier Q.S to……. 1000ml
	Diary No. Date of R & I & fee	Form- 5, Dy. No.247 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551827 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Antibiotic/Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5 litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	I-Enrocol-C Oral Solution (Each 100ml contains: - Enrofloxacin HCl.…10gm Colistin Sulphate…50,000,000IU or 50MIU M/s international pharma Lahore. Registration No.082811
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In response to deficiency letter No.F.1-1/2017/PEC-DRAP (AD PEC-V) dated 23rd November, 2018, you vide letter No. ZPF/Inch (PEC)/005/DRAP/2019, dated nil, revised the label claim/composition as: Each 1000ml oral solution contains: Enrofloxacin …...……100gm Colistin Sulphate…….500MIU • As per enclosure 7, the finished drug product specifications (manufacturer) are provided for your registered drug product Enromars 20% (Oral solution) is mentioned. Please clarify and provide the finished drug product specifications for the applied formulation. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 1000ml oral solution contains:** **Enrofloxacin …...……100gm** **Colistin Sulphate…….500MIU** **Registration letter shall be issued upon submission of following:**	

	• **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of quantities of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
697.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	OXFENDAMARS DRENCH (Oral Suspension)
	Composition	Each 1000ml Oral Suspension contains: Oxfendazole …...……22.65gm (2.265%)
	Diary No. Date of R & I & fee	Form- 5, Dy. No.260 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551825 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished Product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Oxavet suspension of M/s Medi Vet, Lahore Registration No.14551 Oxezole Drench of M/s Islamabad Pharmaceutical Products, Islamabad. Registration No.16233
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• At enclosure 4 regarding manufacturing outlines, in the master formula table, the firm has mentioned Albendazole. • Provide most recent GMP inspection report conducted within last three years. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with BP specifications. Registration letter shall be issued upon submission of following: • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Revised manufacturing outlines (enclosure 4 of the registration application) with correct master formula as albendazole mentioned instead of oxfendazole.** • **Firm shall submit the fee of Rs. 30000 for variation in registration application i.e., correction/change of pharmacological group and correction of above point, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
698.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	LOXYMARS (Water soluble powder)
	Composition	Each 1000gm powder contains: Lincomycin HCl BP…...88gm Spectinomycin BP…….88gm Amoxycillin Trihydrate BP….200gm Vitamin E BP…...5gm
	Diary No. Date of R & I & fee	Form- 5, Dy. No.259 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551822 dated 03-05-2016. (Original Dossier)

	Pharmacological Group	Antibiotic/antibacterial
	Type of Form	Form 5
	Finished Product Specification	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Could not be confirmed
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In initial fee challan and cover letter, the drug product name mentioned as "Doxymars (water soluble powder), while in original Form-5, including its enclosures and differential fee challan, the drug product name is mentioned as "Loxymars". • Provide evidence of drug already approved by DREAP (Generic/Me-too) for the applied formulation along with brand name, registration number and manufacturer name. • Provide most recent GMP inspection report conducted within last three years. • Firm has claimed BP specifications. However, product monograph could not be confirmed in BP.
	Decision: Deferred for: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification from the firm as in the initial fee challan and cover letter, the drug product name mentioned as "Doxymars (water soluble powder), while in original Form-5, including its enclosures and differential fee challan, the drug product name is mentioned as "Loxymars".** • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm has claimed BP specifications for drug product. However, product monograph could not be confirmed in BP.** • **Requisite manufacturing facility (penicillin)**	
699.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	DT300+C (Water soluble powder)
	Composition	Each 1000gm powder contains: Doxycline HCl…...200gm Tylosin Tartrate…100gm Colistin Sulphate….500MIU
	Diary No. Date of R & I & fee	Form- 5, Dy. No.256 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551821 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Antibiotic/antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	AVI-TDC oral powder of M/s Avicenna Laboratories, Sheikhupura. Registration No.071047 TDC-80 Oral powder of M/s Kohinoor Industries, Sahiwal. Registration No. 080965

	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• Firm has claimed USP specifications but product official monograph not available in USP. • Evidence of approval of requisite manufacturing facilities is required. • In finished drug product specifications table, Bromhexine HCl is mentioned. • Provide most recent GMP inspection report conducted within last three years.
	Decision: Approved. Registration letter shall be issued upon submission of following: • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
700.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	FLOMARS (Oral solution)
	Composition	Each 1000ml solution contains: Florfenicol…...230gm Colistin Sulphate…50MIU
	Diary No. Date of R & I & fee	Form- 5, Dy. No.227 dated 25-05-2011 Rs.8000/- dated 24-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551818 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Antibiotic/antibacterial
	Type of Form	Form 5
	Finished Product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml,5 Litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Flotin liquid of M/s D-Maarson Pharmaceuticals, Islamabad. Registration No.072680 Floricent Oral liquid of M/s Decent Pharma, Islamabad. Registration No. 074070 Fentin-23 oral liquid of M/s Nawal pharmaceuticals, Taxila Rawalpindi. Registration No.078257 Fenicol liquid of M/s Univet Pharmaceuticals, Rawalpindi. Registration No.079134
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• The initial challan and cover letter attached bearing the product name as "Albendamars 10% (Oral suspension). Clarification is required. • In response to deficiency letter No.F.1-1/2017/PEC-DRAP (AD PEC-V) dated 23rd November, 2018, you vide letter No. ZPF/Inch (PEC)/008/DRAP/2019, dated nil, had revised the label claim/composition as follows: Each 1000ml solution contains: Florfenicol…...230gm Colistin Sulphate…500MIU • You had claimed BP specifications while official monograph of the product could not be confirmed.

		• Provide most recent GMP compliance inspection report. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Clarification from the firm as in the initial fee challan and cover letter attached bearing the product name as "Albendamars 10% (Oral suspension).** • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of quantities of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
701.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	ALBENDAMARS 2.5% (Oral suspension)
	Composition	Each 1000ml suspension contains: Albendazole…….....25gm
	Diary No. Date of R & I & fee	Form- 5, Dy. No.250 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 04-05-2016 vide Challan No.0551830 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic/dewormers
	Type of Form	Form 5
	Finished Product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml,5 Litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Hanzole 2.5% oral suspension of M/s D-Haans Pharmaceuticals, Azad Kashmir. Registration No.102251 Zolatin Oral suspension of M/s Aamster laboratories, Islamabad. Registration No. 101437
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In response to deficiency letter No.F.1-1/2017/PEC-DRAP (AD PEC-V) dated 23rd November, 2018, you vide letter No. ZPF/Inch (PEC)/009/DRAP/2019, dated nil, had revised the master formula by replacing tartrazine with parrot green coloring agent and excluded the overage. • You have claimed BP specifications for the finished drug product but analytical testing methods are not provided as per BP Monograph. • Provide most recent GMP compliance inspection report. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with USP specifications. Registration letter shall be issued upon submission of following: • **Most recent GMP audit report from QA & LT Division, valid within last three years.**	

	• **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
702.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	TYRODOXIN (Water soluble powder)
	Composition	Each 1000gm powder contains: Doxycycline HCl BP……...200gm Tylosin tartrate BP…….100gm Colistin sulphate BP…… 500MIU Bromhexine HCl BP……... 5gm Phenyl Butazone BP……12gm Carrier QS to …...1000gm
	Diary No. Date of R & I & fee	Form- 5, Dy. No.254 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 03-05-2016 vide Challan No.0551823 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Antibiotic/antibacterial
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Tycoli powder. Each 100gm contains: - Tylosin tartrate B.P (vet) 10gm. Doxycycline HCl B.P (vet) 20gm. Colistin sulphate B.P (vet) 500MIU. Bromohexine B.P (vet) 5gm. Phenyl butazone B.P (vet) 12gm. (anthelmints). Alina Combine pharmaceuticals (pvt) ltd., karachi. Registration no. 048294
	GMP status	
	Remarks of the Evaluator (PEC-XVII)	• Provide evidence of already approved product for the applied formulation (Me-too) as the provided Me-too products formulation are different than the applied formulation. • You have claimed USP specifications, but the official monograph could not be confirmed in USP. • Provide most recent GMP compliance inspection report.
	Decision: Deferred for following: • **Review of applie dfromulation by Expert Working Group.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as the generic/me-too provided has different composition than the applied product.** • **Revision of finished drug specifications as official monograph could not be confirmed in USP while the firm has claimed USP specifications for applied product.**	
703.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	LACTRUM DS (Water soluble powder)
	Composition	Each 1000gm powder contains: Lancomycin HCl BP……...100gm

		Colistin sulphate BP…… 800.000 MIU
	Diary No. Date of R & I & fee	Form- 5, Dy. No.257 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 03-05-2016 vide Challan No.0551824 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Antibiotic/antibacterial
	Type of Form	Form 5
	Finished Product Specification	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Elistine powder Each gm contains: - Lincomycin HCl…….....100mg Colistin sulphate……800,000IU M/s Elegance pharmaceuticals, Distt. Rawalpindi. Registration No. 105026 Tinocin powder Each gm contains: - Lincomycin HCl….....100mg Colistin sulphate…....800,000IU M/s. Bio-labs (Pvt) ltd., Islamabad. Registration no.103974
	GMP status	
	Remarks of the Evaluator (PEC-XVII)	• The initial fee challan and cover letter attached bearing the product name as "Zactrum DS suspension while in differential fee challan, Form-5 and its enclosures, the product mentioned is "Lactrum DS (Water soluble powder). • Provide evidence of already approved product for the applied formulation (Me-too) as the provided Me-too products formulations are different than the applied formulation. • The quantity of Colistin Sulphate mentioned as 800.000MIU and 800,000 MIU in different sections of the dossier. Clarification is required in this regard. • The firm has claimed BP specifications, but the same could not be confirmed in BP. • Manufacturing outlines are not provided. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Deferred for: • **Clarification from the firm required as in the initial fee challan and cover letter, the product mentioned as "Zactrum DS Suspension", while in differential fee challan, Form-5 and its enclosures, the product mentioned as "Lactrum DS (Water soluble powder)". Moreover, the firm has also applied for registration of "Zactrum**	

	suspension" for human use, having composition Trimethoprim……40mg/5ml, Sulphamethoxazole……200mg/5ml mentioned at Sr.No. 1164. • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as the generic/me-too provided has different composition than the applied product.** • **Revision of finished drug product specifications as official monograph could not be confirmed in BP, while the firm has claimed BP specifications.**	
704.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	FIPLOXIN (Water Soluble Powder)
	Composition	Each 1000gm powder contains: Florfenicol……...230gm Oxytetracycline as Hydrochloride…….230gm Carrier QS to …...1000gm
	Diary No. Date of R & I & fee	Form- 5, Dy. No.228 dated 25-05-2011 Rs.8000/- dated 24-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 03-05-2016 vide Challan No.0551820 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Antibiotic/antibacterial
	Type of Form	Form 5
	Finished Product Specification	BP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	FLOWIM ORAL POWDER Each Kg contains: - Oxytetracycline……150gm Florfenicol……..…150gm M/s. Wimits Pharmaceuticals, Lahore. Registration No. 102040 CLOXYFEN WATER SOLUBLE POWDER Each gm contains: - Florfenicol……...150mg Oxytetracycline HCl…...150mg M/s. Fizi Pharmaceuticals and Chemical laboratories, Lahore. Registration No.103831 FLO-OTC WATER SOLUBLE POWDER Each 100g contains: - OxytetracyclineHCl…15gm Florfenicol……...15gm M/s. D-Haans Pharmaceuticals, Azad Kashmir. Registration No. 102224
	GMP status	
	Remarks of the Evaluator (PEC-XVII)	• The initial challan and cover letter attached bearing the product name as "Ciploxin (Oral Solution), while in differential fee challan, Form-5 and its enclosure, the product mentioned is "Fiploxin (water soluble powder). • The Form 5 has also been attached with finished product specifications for Tilmars (Oral solution).

		• You have claimed BP specifications for the applied formulation but the same could not be confirmed in BP. • Provide evidence of approval of required manufacturing facilities by Licensing Division.
	Decision: Deferred for: • **Clarification from the firm is required since in the initial challan and cover letter, the product name mentioned as "Ciploxin (Oral Solution), while in differential fee challan, Form-5 and its enclosure, the product mentioned is "Fiploxin (water soluble powder).** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Finsiehd drug product specifications provided is for Tilmars oral solution.**	
705.	Name and address of manufacturer/ Applicant	Zumars Pharma FTY. Pvt. Ltd. Plot No.02, Malir Industrial Area, Malir, Karachi.
	Brand Name + Dosage Form + Strength	CLOFENDA (Oral Suspension)
	Composition	Each 1000ml suspension contains: Oxfendazole……...22.600gm Oxyclozanide…….60gm Carrier QS to …...1000ml
	Diary No. Date of R & I & fee	Form- 5, Dy. No.255 dated 28-05-2011 Rs.8000/- dated 28-05-2011 (original) Dy.No.377-R&I (DRAP) dated 04-05-2016, Differential fee Rs.12000/- dated 03-05-2016 vide Challan No.0551832 dated 03-05-2016. (Original Dossier)
	Pharmacological Group	Anthelmintic/dewormers
	Type of Form	Form 5
	Finished Product Specification	BP specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5 Litres, De-controlled
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status	Rumenil Drench Each ml contains: - Oxyclozanide…….……62.5mg Oxfendazole……...22.5mg M/s. Mylab (pvt) ltd, Bahawalpur. Registration No. 101458 Oxazide suspension Each 100ml contains: - Oxyclozanide ….……6.250gm Oxfendazole ……...….2.265gm M/s Moreno Iglisias research laboratories (pvt) ltd., Lahore. Registration No. 088849 Oxfendanid oral liquid Each ml contains: - Oxfendazole …22.65mg Oxyclozanide …62.5mg M/s. Bio-oxime pharmaceuticals, Faisalabad. Registration No. 074783 Oxyzan suspension Each 100ml contains: - Oxfendazole…….2.265g Oxyclozanide…….6.25g

		M/s. Univet pharmaceuticals, Rawalpindi. Registration No. 079129 Oxarex drench. Each ml contains: - Oxfendazole 22.65mg. Oxyclozanide 62.50mg. Star laboratories (pvt) ltd., Lahore. Registration No. 031454
	GMP status	Not provided
	Remarks of the Evaluator (PEC-XVII)	• In response to deficiency letter No.F.1-1/2017/PEC-DRAP (AD PEC-V) dated 23rd November, 2018, you vide letter No. ZPF/Inch (PEC)/006/DRAP/2019, dated nil, had revised the master formula by replacing tartrazine with parrot green coloring agent, excluded the overage and revised composition/label claim as; Each 1000ml suspension contains: Oxfendazole…….22.65gm Oxyclozanide…….62.5gm • You have claimed BP specifications for the finished drug product but the same could not be confirmed in BP. • For above revisions, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.
	Decision: Approved with revised label claim as: **Each 1000ml suspension contains:** **Oxfendazole…….22.65gm** **Oxyclozanide…….62.5gm** **Registration letter shall be issued upon submission of following:** • **Most recent GMP audit report from QA & LT Division, valid within last three years.** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of quantities of API), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	

Item No. XVI: Agenda of Evaluator-III

Case No. 01 Registration applications of New section / New License

Case No. 01: M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi

M/s Biogen Life Sciences, Rawalpindi has been granted new license (DML No. 000911) by way of formulation by Licensing division DRAP dated 13-02-2020. Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	Considered till 317th RB meeting		Freshly applied	
	No of molecules	No of products	No of molecules	No of products
Dry Vial section (Cephalosporin)	03	12	-	-

Dry suspension section (Cephalosporin)	01	02	-	-
Capsule section (Cephalosporin)	02	02	-	-
Ampoule Section SVP (General)	05	07	-	-
Capsule section (General)	03	05	-	-
Dry Vial section (General)	03	04	-	-
Soft gel capsule general section	02	03	-	-
Hydrocortisone injection (steroid)	01	03	-	-
Sachet section (General)	01	01	-	-
Dry Vial section (Carbapenem)	02	03	-	-
Cream section (general)	02	02	-	-
Ointment section (General)	01	01	-	-
Lotion section (General)	01	01	-	-
Infusion Section (General)	02	02	-	-
Tablet (General) Section	-	-	01	01

Tablet (General) Section: 01 Molecule / 01 Product

706.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Tablet section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5414: 25-02-2022
	Details of fee submitted	PKR 30,000/-: 30-12-2021
	The proposed proprietary name / brand name	**MOXIGEN 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Moxifloxacin as HCl……400mg
	Pharmaceutical form of applied drug	Yellow Colored, oblong, biconvex film coated tablets
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Avelox 400 mg Tablet **(MHRA** Approved)
	For generic drugs (me-too status)	Avelox Tablet by Bayer

	Name and address of API manufacturer.	Shree Je Laboatory Pvt. Ltd. C-24 & 25 RIICO Industrial Area, Sotanala, Behror, District Alwar, Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Moxiget Tablet of Getz Pharma. Firm has submitted results of CDP studies in three dissolution medium for their product against Moxiget Tablet of Getz Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Shree Je Laboatory Pvt. Ltd. C-24 & 25 RIICO Industrial Area, Sotanala, Behror, District Alwar, Rajasthan India.
API Lot No.	MXYUSU001
Description of Pack (Container closure system)	Glass vials
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	T-002	T-003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	06-04-2021	06-04-2021	06-04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 2019/203) issued by Drugs control Organization, Government of Rajasthan India dated 07-02-2019. The GMP certificate is valid upto three years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 08-03-2021 specifying purchase of 2.5Kg Moxifloxacin. Firm has also submitted copy of DHL invoice number 270400305DTD.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC system are not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data of verification of analytical procedure of drug substance	Firm has submitted report of verification studies of the drug substance from Biogen Life Sciences.
2.	Submit stability study data of drug substance till claimed shelf life as per zone IV-A conditions, since the submitted stability study data is till 1 year only.	Firm has submitted API stability data till 1 year.
3.	Justify why the pharmaceutical equivalence studies were conducted against the comparator product instead of using innovator / reference product.	Due to easily Access of the comparator Moxiget 400mg Tab in market that way the firm (Biogen Life Sciences) preform Pharmaceutical Equivalence & Comparative Dissolution studies with Moxiget 400mg Tablet

Decision: Approved.

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

- **Manufacturer shall submit Pharmaceutical Equivalence and Comparative dissolution profile studies with Innovator product before issuance of registration letter.**

Case No. 02 Registration applications on Form5F.

a. New cases of local manufacturing

707.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saaaf Pharmaceutical Industries. 15-Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 21-04-2017 is submitted
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25417: 13-09-2021
	Details of fee submitted	PKR 75,000/-: 02-09-2021
	The proposed proprietary name / brand name	**SAFENEM 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……..500mg (Blended with sodium carbonate)
	Pharmaceutical form of applied drug	Glass vial filled with almost white powder along with 10ml ampoule of WFI further packed in unit carton.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.

	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Meronem 500mg injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
API Lot No.	UIMRPS19021
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MR-001	MR-002	MR-003
Batch Size	350 vials	350 vials	350 vials
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	07-01-2020	07-01-2020	07-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DC/A-1/WHO-GMP/2020/1961) issued by Drugs control organization, Governmnet of Rajasthan dated 09-12-2020. The certificate is valid till 26-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of meropenem 3Kg from M/s Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India issued by AD (I&E) DRAP field office. The license was issued on 02-01-2020. • Firm has submitted copy of commercial invoice dated 02-01-2020 specifying import of 3Kg meropenem. The invoice is signed by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for only single day 01-07-2020.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The applied product to be manufactured by M/s Bio-Next Pharmaceuticals have already been approved by Registration Board in its 296th meeting based on the data of same trial batches of drug product as submitted in the instant case. The details of the already approved product in 296th meeting are as follows:

Applicant firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Manufacturer firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Brand Name	MENEPOR 500 mg Injection IV
Batch No. of drug product	MR-001 (350 vials), MR-002 (350 vials), MR-003 (350 vials)

Case No.	14
Registration Board meeting	296th meeting of Registration Board held on (8th, 9th & 10th September 2020)

- The stability data of commercial batches of the same formulation manufactured by M/s Bio-Next Pharmaceuticals have also already been approved by Registration Board in its 320th meeting based The details of the already approved product in 320th meeting are as follows:

Applicant firm	M/s Gray's Pharmaceuticals Plot No. 2, Street # N-3, National Industrial Zone Rawat Islamabad.
Manufacturer firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Brand Name	GRAYNEM 500 mg Injection IV
Batch No. of drug product	21E001 (14084 vials), 21E002 (14084 vials), 21E005 (14084 vials)
Case No.	197
Registration Board meeting	320th meeting of Registration Board held on (29th-31st August, 2022)

- Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.**

708.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saaaf Pharmaceutical Industries. 15-Nowshera Industrial Estate, Risalpur**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 21-04-2017 is submitted
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25418: 13-09-2021
	Details of fee submitted	PKR 75,000/-: 02-09-2021
	The proposed proprietary name / brand name	**SAFENEM 1gm IV Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……..1g (Blended with sodium carbonate)
	Pharmaceutical form of applied drug	Glass vial filled with almost white powder along with 20ml ampoule of WFI further packed in unit carton.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their

		product against the comparator i.e. Meronem 1g injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.		
API Lot No.	UIMRPS19021		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MR-004	MR-005	MR-006
Batch Size	350 vials	350 vials	350 vials
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	07-01-2020	07-01-2020	07-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DC/A-1/WHO-GMP/2020/1961) issued by Drugs control organization Governmnet of Rajasthan dated 09-12-2020. The certificate is valid till 26-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of meropenem 3Kg from M/s Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India issued by AD (I&E) DRAP field office. The license was issued on 02-01-2020. • Firm has submitted copy of commercial invoice dated 02-01-2020 specifying import of 3Kg meropenem. The invoice is signed by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for only single day 01-07-2020.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The applied product to be manufactured by M/s Bio-Next Pharmaceuticals have already been approved by Registration Board in its 296th meeting based on the data of same trial batches of drug product as submitted in the instant case. The details of the already approved product in 296th meeting are as follows:

Applicant firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Manufacturer firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Brand Name	MENEPOR 1g Injection IV
Batch No. of drug product	MR-004 (350 vials), MR-005 (350 vials), MR-006 (350 vials)
Case No.	15
Registration Board meeting	296th meeting of Registration Board held on (8th, 9th & 10th September 2020)

- The stability data of commercial batches of the same formulation manufactured by M/s Bio-Next Pharmaceuticals have also already been approved by Registration Board in its 320th meeting based The details of the already approved product in 320th meeting are as follows:

Applicant firm	M/s Gray's Pharmaceuticals Plot No. 2, Street # N-3, National Industrial Zone Rawat Islamabad.
Manufacturer firm	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
Brand Name	GRAYNEM 1g Injection IV
Batch No. of drug product	21E008 (10563 vials), 21E009 (10563 vials), 21E010 (10563 vials)
Case No.	198
Registration Board meeting	320th meeting of Registration Board held on (29th-31st August, 2022)

Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.**

709.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 25-03-2021.
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry vial section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19886: 15-07-2021
	Details of fee submitted	PKR 50,000/-: 27-04-2021
	The proposed proprietary name / brand name	**COLIGEN Injection 1 MIU (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Colistimethate sodium……1 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials with grey rubber stopper with an aluminium cap
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises (Reg #093937)
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator Colistimethate sodium 1MIU Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.		
API Lot No.	HN190202		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T010	T011	T012
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	16-02-2020	17-02-2020	18-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20190058) issued by CFDA China. The certificate is valid till 14-08-2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 02-02-2020 specifying import of 0.5Kg Colistimethate. The invoice is not attested by AD (I&E) DRAP Field office. The firm has submitted copy of DHL invoice (Invoice No. 20HS-091) for the import of drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, and pictures of the petri dishes showing zone of inhibitions following the microbial assay.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- The submitted data was already approved by Registration Board. The details of already approved product is as under:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	LISTIM Injection 1 MIU (IV)
Batch No. of drug product	T010 (500 vials), T011 (500 vials), T012 (500 vials)
Case No.	235
Registration Board meeting	297th meeting of Registration Board.

Decision: Approved.

- **Firm shall submit differential fee 25,000/- for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

710.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

		Firm has submitted copy of contract manufacturing agreement with applicant firm dated 25-03-2021.
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry vial section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19887: 15-07-2021
	Details of fee submitted	PKR 50,000/-: 27-04-2021
	The proposed proprietary name / brand name	**COLIGEN Injection 2 MIU (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Colistimethate sodium……2 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials with grey rubber stopper with an aluminium cap
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises (Reg #094757)
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator Colistimethate sodium 2MIU Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.		
API Lot No.	HN190202		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T013	T014	T015
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	16-02-2020	17-02-2020	18-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20190058) issued by CFDA China. The certificate is valid till 14-08-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 02-02-2020 specifying import of 0.5Kg Colistimethate. The invoice is not attested by AD

		(I&E) DRAP Field office. The firm has submitted copy of DHL invoice (Invoice No. 20HS-091) for the import of drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, and pictures of the petri dishes showing zone of inhibitions following the microbial assay.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- The submitted data was already approved by Registration Board. The details of already approved product is as under:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	LISTIM Injection 2 MIU (IV)
Batch No. of drug product	T013 (500 vials), T014 (500 vials), T015 (500 vials)
Case No.	236
Registration Board meeting	297th meeting of Registration Board.

Decision: Approved.

- **Firm shall submit differential fee 25,000/- for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

711.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 25-03-2021.

	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry vial section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19888: 15-07-2021
	Details of fee submitted	PKR 50,000/-: 27-04-2021
	The proposed proprietary name / brand name	**COLIVAL Injection 1 MIU (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Colistimethate sodium……1 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials with grey rubber stopper with an aluminium cap
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises (Reg #093937)
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator Colistimethate sodium 1MIU Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.		
API Lot No.	HN190202		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T010	T011	T012
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	16-02-2020	17-02-2020	18-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20190058) issued by CFDA China. The certificate is valid till 14-08-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 02-02-2020 specifying import of 0.5Kg Colistimethate. The invoice is not attested by AD (I&E) DRAP Field office. The firm has submitted copy of DHL invoice (Invoice No. 20HS-091) for the import of drug substance.

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

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- The submitted data was already approved by Registration Board. The details of already approved product is as under:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	LISTIM Injection 1 MIU (IV)
Batch No. of drug product	T010 (500 vials), T011 (500 vials), T012 (500 vials)
Case No.	235
Registration Board meeting	297th meeting of Registration Board.

Decision: Approved.

- **Firm shall submit differential fee 25,000/- for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi**

712.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 25-03-2021.
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.

	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry vial section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19889: 15-07-2021
	Details of fee submitted	PKR 50,000/-: 27-04-2021
	The proposed proprietary name / brand name	**COLIVAL Injection 2 MIU (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Colistimethate sodium……2 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials with grey rubber stopper with an aluminium cap
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises (Reg #094757)
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator Colistimethate sodium 2MIU Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.		
API Lot No.	HN190202		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T013	T014	T015
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	16-02-2020	17-02-2020	18-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20190058) issued by CFDA China. The certificate is valid till 14-08-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 02-02-2020 specifying import of 0.5Kg Colistimethate. The invoice is not attested by AD (I&E) DRAP Field office. The firm has submitted copy of DHL invoice (Invoice No. 20HS-091) for the import of drug substance.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with raw data sheets, and pictures

	chromatograms, Raw data sheets, COA, summary data sheets etc.	of the petri dishes showing zone of inhibitions following the microbial assay.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- The submitted data was already approved by Registration Board. The details of already approved product is as under:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	LISTIM Injection 2 MIU (IV)
Batch No. of drug product	T013 (500 vials), T014 (500 vials), T015 (500 vials)
Case No.	236
Registration Board meeting	297th meeting of Registration Board.

Decision: Approved.

- **Firm shall submit differential fee 25,000/- for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

713.	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Biogen Pharma, 8Km Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16107: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 27-04-2021
	The proposed proprietary name / brand name	**BIOTROXONE 2gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……2g
	Pharmaceutical form of applied drug	Sterile white to off white / yellowish crystalline powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Rocephin injection by Roche.
	Name and address of API manufacturer.	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability. Firm has also submitted compatibility studies of the drug product along with the recommended diluent i.e. water for injection.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in USP for their product against the comparator i.e. Oxidil 2g Injection of M/s Sami Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.		
API Lot No.	00421/002/2019		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	20-02-2020	20-02-2020	20-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 10Kg Ceftriaxone sodium (sterile) dated 19-02-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- The submitted data was already approved by Registration Board. The details of already approved product is as under:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	CARE 2g Injection IV
Batch No. of drug product	001 (400 vials), 002 (400 vials), 003 (400 vials)
Case No.	227
Registration Board meeting	297th meeting of Registration Board.

Decision: Approved.

- **Firm shall submit differential fee 25,000/- for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit full fee as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021 since the title of the manufacturer has been changed from Biogen Pharmaceuticals to Biogen Life sciences.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

714.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilshire Laboratories (Pvt) Ltd. 124/1-Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	M/s Wilshire Laboratories (Pvt) Ltd. 124/1-Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued based on inspection dated 08-08-2019. The GMP certificate specifies Dry Powder Injection (General) Section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued based on inspection dated 08-08-2019. The GMP certificate specifies Dry Powder Injection (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33258 dated 08-12-2021
	Details of fee submitted	Rs. 30,000/- Dated 21-05-2021

	The proposed proprietary name / brand name	**PETRONEL 2MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium …… 2MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Nogotex injection by Nabiqasim
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing, Fuzhou City Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product

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

STABILITY STUDY DATA

Manufacturer of API	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing, Fuzhou City Fujian Province China.		
API Lot No.	CMS1811008		
Description of Pack (Container closure system)	Clear glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	13-10-2020	13-10-2020	13-10-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy og DML of the firm (permit number Min 20160089) issued and available online on NMPA China Website. The certificate is valid till 21-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 3.005Kg Colistimethate sodium. The invoice is attested by AD (I&E) DRAP Lahore dated 27-02-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted Stability data along-with HPLC chromatograms and raw data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not available
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Observation	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by	Firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.

	both Drug substance & Drug Product manufacturer is required."	
2.	Provide verification studies of drug substance from drug product manufacturer in section 3.2.S.4.3.	Firm has submitted verification studies of drug substance from drug product manufacturer.
3.	Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product in section 3.2.S.4.4, since COA of different batches is provided in this section.	Firm has submitted COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product having batch number CMS1811008.
4.	Provide details including batch number, expiry date and manufacturer of the reference product against which pharmaceutical equivalence studies have been carried out.	Pharmaceutical equivalence is established by comparing ingredients of Colistimethate sodium 2 MIU Injection (Powder for solution for injection) manufactured by "XELLIA PHARMACEUTICAL APS, DENMARK". This medicinal product is authorized in the Member States of the EEA like in France & UK.
5.	Justify why pharmaceutical equivalence studies does not include complete testing as per USP monograph.	As this product specification comply with the Pharmacopoeial reference & all parameters verified with the product specifications as well. So, Pharmacopoeial equivalence does not required in this scope.
6.	Provide details in sections 3.2.P.2.6 as per the CTD guidance document which specifies that "Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product."	As no excipient is added with API in manufacturing process of Drug Product so, compatibility studies are not required.
7.	Your manufacturing method specifies that the product is lyophilized within the vials after solution preparation and filling while your approved manufacturing facility is for dry powder vial general. Justify where the manufacturing of applied product was carried out.	The reference Product as well as our Product is not lyophilized.
8.	Justify why your drug product specification does not contain pH and free colistin test as specified in USP monograph.	pH and free colistin tests are missed due to typographical mistake. Updated Analytical method is provided.
9.	The analytical method for drug product contains bioassay method while the verification studies are carried out usig HPLC method. Justification is required in this regard.	The Drug Product is analyzed by Bioassay as mentioned in analytical method but HPLC method is erroneously added in Verification studies due to typographical mistake.
10.	Provide COA of reference standard actually used in the analysis of drug product.	Lot No. R07870 of Colistimethate Sodium USP Reference standard is used.
11.	Provide BMR of three stability batches.	Firm has submitted copy of BMR of 3 batches.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**

715.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilshire Laboratories (Pvt) Ltd. 124/1-Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.**
	Name, address of Manufacturing site.	M/s Wilshire Laboratories (Pvt) Ltd. 124/1-Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued based on inspection dated 08-08-2019. The GMP

		certificate specifies Dry Powder Injection (General) Section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued based on inspection dated 08-08-2019. The GMP certificate specifies Dry Powder Injection (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 33259 dated 08-12-2021
	Details of fee submitted	Rs. 30,000/- Dated 21-05-2021
	The proposed proprietary name / brand name	**PETRONEL 3MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium …… 3MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Nogotex injection by Nabiqasim
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing, Fuzhou City Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ±

		5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Colistimethate sodium 3MIU Injection Pan Medica
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing, Fuzhou City Fujian Province China.		
API Lot No.	CMS1811008		
Description of Pack (Container closure system)	Clear glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	13-10-2020	13-10-2020	13-10-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy og DML of the firm (permit number Min 20160089) issued and available online on NMPA China Website. The certificate is valid till 21-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 3.005Kg Colistimethate sodium. The invoice is attested by AD (I&E) DRAP Lahore dated 27-02-2020.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted Stability data along-with HPLC chromatograms and raw data sheets.

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

Evaluation by PEC:

Sr. No	Observation	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of drug substance from drug product manufacturer in section 3.2.S.4.3.	Firm has submitted verification studies of drug substance from drug product manufacturer.
3.	Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product in section 3.2.S.4.4, since COA of different batches is provided in this section.	Firm has submitted COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product having batch number CMS1811008.
4.	Provide details including batch number, expiry date and manufacturer of the reference product against which pharmaceutical equivalence studies have been carried out.	Pharmaceutical equivalence is established by comparing ingredients of Colistimethate sodium 2 MIU Injection (Powder for solution for injection) manufactured by "XELLIA PHARMACEUTICAL APS, DENMARK". This medicinal product is authorized in the Member States of the EEA like in France & UK.
5.	Justify why pharmaceutical equivalence studies does not include complete testing as per USP monograph.	As this product specification comply with the Pharmacopoeial reference & all parameters verified with the product specifications as well. So, Pharmacopoeial equivalence does not required in this scope.
6.	Provide details in sections 3.2.P.2.6 as per the CTD guidance document which specifies that "Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product."	As no excipient is added with API in manufacturing process of Drug Product so, compatibility studies are not required.
7.	Your manufacturing method specifies that the product is lyophilized within the vials after solution preparation and filling while your approved manufacturing facility is for dry powder vial general. Justify where the manufacturing of applied product was carried out.	The reference Product as well as our Product is not lyophilized. As per imported API the appearance is "white to slightly yellow odourless fine powder"
8.	Justify why your drug product specification does not contain pH and free colistin test as specified in USP monograph.	pH and free colistin tests are missed due to typographical mistake. Updated Analytical method is provided.
9.	The analytical method for drug product contains bioassay method while the verification studies are carried out usig HPLC method. Justification is required in this regard.	The Drug Product is analyzed by Bioassay as mentioned in analytical method but HPLC method is erroneously added in Verification studies due to typographical mistake.
10.	Provide COA of reference standard actually used in the analysis of drug product.	Lot No. R07870 of Colistimethate Sodium USP Reference standard is used.
11.	Provide BMR of three stability batches.	Firm has submitted copy of BMR of 3 batches.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**

716.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries (Pvt) Ltd. 17/24 Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt) Ltd. 17/24 Korangi Industrial Area Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued based on inspection dated 19-09-2020. The GMP certificate specifies Small Volume Lyophilized Injectable Section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued based on inspection dated 19-09-2020. The GMP certificate specifies Small Volume Lyophilized Injectable Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28452 dated 15-10-2021
	Details of fee submitted	Rs. 75,000/- Dated 28-05-2021
	The proposed proprietary name / brand name	**NOGOTEX Injection 4.5MIU**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium (lyophilized powder) …… 4.5MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	White color lyophilized cake / powder filled in vials
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Coly-Mycin® M Parenteral 150 mg colistin base activity **USFDA** Approved
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing, Fuzhou City Fujian Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

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

STABILITY STUDY DATA

Manufacturer of API	Livzon Group Fuzhou Fuxing Pharmaceutical Co. Ltd. No. 8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing, Fuzhou City Fujian Province China.		
API Lot No.	CMS2005002		
Description of Pack (Container closure system)	Clear glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	373DS01	373DS02	373DS03

Batch Size	200 Vials	200 Vials	200 Vials
Manufacturing Date	10-2020	10-2020	10-2020
Date of Initiation	07-10-2020	07-10-2020	07-10-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted online copy of manufacturing license of the firm having permit number 20160089 issued by NMPA China. The license is valid till 21-09-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 1Kg Colistimethate sodium. The invoice is attested by AD (I&E) DRAP dated 11-09-2020 for batch # CMS2005002.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted raw data sheets for calculation of results of assay.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not available
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The innovator product Coly-Mycin® M Parenteral (Colistimethate for Injection, USP) is approved by USFDA wherein Each vial contains colistimethate sodium or pentasodium colistinmethanesulfonate (150 mg colistin base activity). As per MHRA and EU approved conversion table for dose of colistimethate sodium (CMS) 150mg CBA is equivalent to 4500000 (4.5MIU).

Sr. No	Observation	Response by the firm
1.	Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product in section 3.2.S.4.4, since COA of different batches is provided in this section.	COA of relevant batch of drug substance (Batch No. CMS 2005002) used in manufacturing of batches of drug product is enclose
2.	Provide details including batch number, expiry date and manufacturer of the reference product against which pharmaceutical equivalence studies have been carried out.	Xylistin 4.5 MIU (Colistimethate Sodium 4.5MIU) reference product use in pharmaceutical equivalence studies. Details are as follows: Manufactured By: Cipla LTD. Batch No.: L610246 Mfg. Date: Jun.21 Exp. Date: May 23
3.	Justify why pharmaceutical equivalence studies does not include complete testing as per USP monograph.	Firm has now submitted pharmaceutical equivalence with complete tests as per USP
4.	Provide details in sections 3.2.P.2.6 as per the CTD guidance document which specifies that "Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product."	Firm has submitted compatibility studies /In-Use studies for the Colistimethate sodium injection.
5.	Provide COA of reference standard actually used in the analysis of drug product.	Firm has submitted COA of reference standard along with standardization record.
6.	Justify why sterility test is not performed during stability studies.	Trial batches for stability studies were manufactured in Research & Development Department, that's why sterility studies were not conducted, however for

		commercial batches sterility testing will be perform before QC release as well as on stability studies. Firm has also submitted the following response: NabiQasim is the only company that has a highly automated Lyophilized vial inspection machine and this facility has 100% non-destructive vial testing ensuring that oxygen and moisture content is not present in vials that could lead to degradation of the active substances causing a loss in efficacy and quality of the product. Colistimethate Sodium 4.5 MIU for development studies was manufactured in the R&D Lab facility by using an R&D dedicated Lab scale Lyophilizer. As your good self-ask about sterility testing of Colistimethate Sodium 4.5 MIU on development batches, now we have developed a trial batch of Colistimethate Sodium 4.5MIU in our state-of-the-art commercial Lyophilized facility and **till to date** sterility of product has been found satisfactory. Finished product Specifications to conduct sterility testing on Colistimethate Sodium Injection 4.5 MIU is enclosed for your ready reference for QC commercial release and stability batches. Moreover, NabiQasim Industries Private Limited already manufacturing and marketing Lyophilized Branded Generic Products as follows: • Remdesivir 100mg Injection • Colistimethate Sodium 1MIU • Colistimethate Sodium 2 MIU • Colistimethate Sodium 3 MIU
7.	Justify how 300 vials batch size is sufficient enough to complete the accelerated and real time stability studies of the product.	Please note that actual batch size as per BMR of stability batches is 200 vials. Batch size mention on stability summary sheet is 300 vials which was a typo-error. As per stability protocol 190 vials were collected for stability studies. Revise stability summary sheet is enclose for your ready reference. Justification letter for 200 vials of each batch is sufficient enough for stability studies. **Total Vials require** Description/Appearance = 01 pH = 01 Loss on Drying = 01 Free Colistin = 01 Bacterial Endotoxin Test = 02 Assay = 02 **Total Vials = 08** **Total Intervals (Real Time Stability)** = 06 Total Vials Required for Real Time Stability Studies =6*08 =48 vials **Total Intervals (Accelerated Stability)** = 02 Total Vials Required for Accelerated Condition Stability Studies =02*08 =16 vials Although batch size is of 200 Vials, we place 130 Vials for Real Time condition stability studies and 60 Vials for Accelerated Condition stability studies which are sufficient enough to conduct stability studies till proposed shelf life period.

8.	Specify where the manufacturing of trial batches was carried out including details of the equipment as well as its minimum capcity to justify the sterile solution preparation for 300 vials.	Manufacturing of trial batches was carried out in R&D facility having R&D Lab scale lyophilizer equipment and approximately 600 vials can be lyophilized at a time.
9.	Submit Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted "VAI" inspection report of FDA does not specify the exact address of manufacturing site.	Firm has submitted online copy of manufacturing license of the firm having permit number 20160089 issued by NMPA China. The license is valid till 21-09-2025.
10.	Provide BMR of three stability batches.	Firm has submitted BMR of three stability batches.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**

717.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 02-08-2021 is submitted.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-03-2022 based on inspection dated 11-02-2019. As per the certificate, it was valid till 09-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML of M/s Vision Pharmaceuticals DML No 000517 dated 07-06-2021. The letter specifies Liquid Injectable Vial SVP (General) Section. Firm has also submitted copy of letter dated 09-12-2021 which specifies that CLB in its 283rd meeting held on 28th October 2021 also approved renewal of DML for Liquid Injectable (LVP) General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24361: 03-09-2021
	Details of fee submitted	PKR 75,000/-: 06-08-2021
	The proposed proprietary name / brand name	**JYTHON 200mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 100ml Contains: Linezolid……200mg

	Pharmaceutical form of applied drug	Liquid infusion
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use
	Reference to Finished product specifications	In-house specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zyvox IV **(USFDA** Approved)
	For generic drugs (me-too status)	Nezkil Infusion by Continental pharma
	Name and address of API manufacturer.	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Nezkil infusion of Continental Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.		
API Lot No.	OP-LID/07/18/077		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	1018904	1018905	1018906
Batch Size	3000 Vials	3000 Vials	3000 Vials
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	26-10-2018	26-10-2018	26-10-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License Retention Certificate for License number 3/NG/TS/2015/B/G of M/s Optrix Laboratories Pvt Ltd. The license is permitted with validity upto 02-06-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Clearance certificate dated 06-09-2018 specifying import of 50Kg Linezolid. The clearance certificate is issued by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC system are not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Observation	Response by the firm
1.	The drug substance manufacturer has specified HPLC test for assay of drug substance while the drug product manufacturer has specified UV method for assay of drug substance. Justify how drug product manufacturer can adopt different test for assay method from that recommended by the drug substance manufacturer.	The drug substance testing was done by UV method at that time, but currently we are using HPLC method for both API and finished product. Revised SOP is submitted by the firm.
2.	Justify why the pharmaceutical equivalence studies were conducted against the comparator product instead of using innovator / reference product. Further justify why pharmaceutical equivalence does not include all quality tests.	Pharmaceutical equivalence study was done against Nezkil of continental pharma as it is among brand leaders in Pakistan and registered/approved by DRAP. All tests have been performed.
3.	Justify why the test for filled volume is not specified in the specifications of the drug product	The filled volume test was performed and the test reports are attached.

	although this test is recommended in general monograph of official pharmacopoeia.	
4.	Justify why terminal sterilization is not performed for the said product although being the method of choice for sterilization.	Terminal sterilization is performed and also mentioned in BMR.
5.	Justify the pH of the drug product from 4.4 to 5.5 since the pH range recommended by the innovator's product is 4.4-5.2.	Linezolid infusion batches kept on stability have pH almost in the range of 4.6 to 4.8, and this is in limit of 4.4 to 5.2, However, we will Revise the pH limit as according to innovator specs and will revise the testing SOP.
6.	Justify the analytical method for assay testing of the drug product which is based on UV method since the innovator's product as well as the drug substance manufacturer specify HPLC method for assay test.	As this product is not pharmacopeial, so previously batches were tested according to the method of UV spectrophotometer. Hence, the submitted stability batches were tested according to the previous testing method. Then, we had shifted to HPLC method effective from 13-9-2021, for which we have shared the revised SOP now. We are following this method for stability studies and stability data of batches tested according to this method. Revised SOP is attached

Decision: Approved with Innovator's specifications.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit fee 7,500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Firm shall submit data of HPLC testing on recently manufactured batches of the applied drug product before issuance of Registration letter.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.**

718.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 29-05-2020 is submitted.
	GMP status of the firm	**Global pharmaceuticals:** GMP certificate issued on the basis of inspection dated 03-01-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 24852: 08-09-2021
	Details of fee submitted	PKR 75,000/-: 28-08-2021
	The proposed proprietary name / brand name	**CIMIPEN 500mg/500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).……500mg Cilastatin (as sodium)……500mg
	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Onem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai City Guangdong Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Primaxin Injection IV of Merck & Co.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai City Guangdong Province China		
API Lot No.	3951902009 3951903005		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19G096	19G097	19G098
Batch Size	9041 vials	9041 vials	9041 vials
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	07-08-2019	07-08-2019	23-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: • The HPLC software is 21 CFR compliant. • The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20180909) issued by China Food and Drugs Administration. The certificate is valid till 12-05-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**3951902009:** Firm has submitted copy of commercial invoice cleared dated 27-06-2019 specifying import of 50Kg imipenem and cilastatin for injection. The commercial invoice is attested by AD (I&E) DRAP field office.
		3951903005: No evidence of import is submitted for this batch.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

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

Evaluation by PEC:

Firm was communicated the following decision of Registration Board

Registration Board in its 313th meeting considered the case of Imipenem / Cilastatin injection manufactured by Global Pharmaceuticals, Islamabad wherein the Board decided as under:
"Registration Board deliberated that the commercial batches manufactured by the manufacturer i.e. Global Pharmaceuticals was not developed and tested as per the USP monograph. Keeping in view the USP monograph, public assessment report of the innovator product and the data submitted by the firm, the Board decided to defer the case and advised the manufacturer to perform product development studies keeping in view the innovator product and product testing and stability studies by complying USP monograph and submit data upon completion of 6 months stability studies".

In response the firm has submitted complete new CTD (Form 5F) with new data. The evaluation of newly submitted data is as under:

Dy. No. and date of submission	
Details of fee submitted	Fee for revised stability batches not submitted
The proposed proprietary name / brand name	**CIMIPEN 500mg/500mg Injection**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem monohydrate eq. to imipenem…….500mg Cilastatin Sodium eq. to Cilastatin ……500mg
For generic drugs (me-too status)	Cilapen 500mg Injection of Bosch Pharmaceuticals Reg No. 048491
Name and address of API manufacturer.	M/s ACS DOBFAR S.p.A Viale Addetta 2a/12-3/5 20067 Tribiano, Milano- Italy
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: Temp.: 30°C ± 2°C, RH: 65% ± 5% for 36 month Accelerated: Temp.: 40°C ± 2°C, RH: 75% ± 5%for 6 months

	Batches: (990068 8004 2, 990068 8005 2, 990068 8006 2)
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence of their developed formulation Cinam 500mg injection (B #22A338) with reference product Cilapen 500mg Injection Batch No: CP200034 by Bosch Pharmaceuticals. The results showed that both test and reference products were comparable.
Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s ACS DOBFAR S.p.A Viale Addetta 2a/12-3/5 20067 Tribiano, Milano- Italy.	
API Lot No.	990068-0008-E1	
Description of Pack (Container closure system)	White to pale yellow color powder filled in clear glass vial, packed in Unit carton (1's)	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 24 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)	
Batch No.	22A337	22A338
Batch Size	5550 vials	5550 vials
Manufacturing Date	01-2022	01-2022
Date of Initiation	22-01-2022	22-01-2022
No. of Batches	02	

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Italian pharmaceutical Agency valid till 26/03/2025 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of and attested ADC (I&E) DRAP, Islamabad dated 02-06-2021 for Imipenem and cilastatin sodium sterile Batch No. 990068 0008 E1.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR

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

Remarks of Evaluator:

- The diluent for reconstitution used by the firm is 10ml WFI while innovator and reference product recommend 10ml 0.9% NaCl injection.
- Firm is using 1081mg/ vial which is not justified keeping in view both drug substances are available as salt form where 530mg imipenem monohydrate is equivalent to 500 mg imipenem and 530 mg cilastatin sodium salt is equivalent to 500mg cilastatin. Furthermore, the COA of API depicts that the maximum percentage of both API could be 96.6% (48.3 % of individual API).
- The panel has conducted capacity assessment of the firm, M/s Global Pharmaceuticals on 21.10.2022 for following sections and has submitted report to PE&R Division for further processing:

1. Dry Powder Injection (Cephalosporin)
2. Dry Powder Injection (Penicillin)
3. Dry Powder Injection (Carbapenem)
4. Liquid Injection Ampoule (General)

Discussion: Registration Board was apprised that the firm has submitted response against the above mentioned observations on the day of meeting in which firm has submitted that in BMR they have mentioned 10ml WFI as diluent, however from now onwards they will use 10ml 0.9% NaCl solution as diluent as per the recommendations of innovator's drug product. Furthermore, the firm has also submitted calculation for fill weight of drug substance in the vials in which they have taken sodium contents as per innovator's drug product claim instead of using sodium contents as per the drug substance.

Decision: Approved.

- **M/s Global shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent along with BMR of recently manufactured batches from M/s Global Pharmaceuticals, as evidence of use of the recommended diluent before issuance of Registration letter.**
- **Firm shall use correct fill weight per vial considering the sodium content as per the drug substance manufacturer's claim for the commercial batches and submit BMR of recently manufactured batches from M/s Global Pharmaceuticals as evidence of correct fill weight before issuance of Registration letter.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit full fee 75,000/- for revision of stability study data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with Pharmaceutical equivalence studies against the innovator product..**
- **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.**

719.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sigma Pharma International (Pvt) Ltd. Plot # E-50, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Sigma Pharma International (Pvt) Ltd. Plot # E-50, North Western Industrial Zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-11-2020. The letter specifies Tablet (General) Section.

	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-11-2020. The letter specifies Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24405: 20-11-2019
	Details of fee submitted	PKR 20,000/-: 19-11-2019
	The proposed proprietary name / brand name	**TRED SR 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated sustained release tablet contains: Tramadol HCl……100mg
	Pharmaceutical form of applied drug	White color round shaped film coated sustained release tablet with line of bisection on one side.
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Tramal SR Tablet by Searle
	Name and address of API manufacturer.	Supriya Lifescience Ltd., A-5/2, Lote Parshuram Industrial Area, M.I.D.C. Taluka – Khed, District – Ratnagiri, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 12 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Tramal SR Tablet by Searle. Firm has submitted results of CDP for their product against the comparator product Tramal SR Tablet by Searle. The CDP is performed in 3 dissolution medium.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Supriya Lifescience Ltd., A-5/2, Lote Parshuram Industrial Area, M.I.D.C. Taluka – Khed, District – Ratnagiri, Maharashtra, India		
API Lot No.	SLL/TDM/0121006		
Description of Pack (Container closure system)	Alu-PVC		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	6452 Tablet	6452 Tablet	6452 Tablet
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	06-07-2021	20-07-2021	28-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No PSI of the firm has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 6099317) issued by Food & Drugs Administration (Maharashtra State) India. The certificate is valid till 29-04-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice from Globe Chemicals GmbH cleared by AD (I&E) DRAP dated 22-04-2021. The invoice declare purchase of 300Kg Tramadol HCl.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted stability study data of 3 batches along with water loss test at each time

	chromatograms, Raw data sheets, COA, summary data sheets etc.	point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC system is not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Firm has submitted initial application on Form 5F on 20-11-2019 before the start of process of CTD pre-submission screening. The initial application was without any product development or stability study data. Later in response to the letter of shortcoming the firm submitted product development and stability study data on 05-10-2021.
- The real time stability study data of API is till 12 months only.
- GMP certificate of API was valid till 29-04-2022.
- Real time stability study data was conducted at 0, 6, 12, 18, 24 month and does not include testing at 3 and 9 months.

Decision: Registration Board observed that the firm has submitted various documents at different time intervals and that completely compiled application is not submitted. The Board after thorough deliberation decided to defer the case for submission of complete application on Form 5-F as per the guidance document approved by Registration Board.

720.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 28-05-2021.
	GMP status of the firm	**English Pharmaceutical:** GMP certificate issued based on inspection dated 06-01-2018
	Evidence of approval of manufacturing facility	Firm (M/s English Pharmaceuticals) has submitted copy of renewal of DML letter dated 09-03-2015 specifying Dry powder injectable vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23531 dated 27-08-2021
	Details of fee submitted	Rs. 75,000/- Dated 12-07-2021
	The proposed proprietary name / brand name	**COLIZONE 2MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium …… 2MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Powder for solution for injection

	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Colistim injection by Biocare pharmaceuticals
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang Hebei Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions**.**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Colixin Injection of Pharmis Biofamaceutica
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang, Hebei Province, China
API Lot No.	HN180401
Description of Pack (Container closure system)	Clear glass vial
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 1, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	
Batch Size	2700 packs	2700 packs	
Manufacturing Date	06-2020	06-2020	
Date of Initiation	13-07-2020	13-07-2020	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. HE20190058) issued by China Food and Drug Administration valid upto 14-08-2024 is submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 8Kg Colistimethate sodium. The invoice is attested by AD (I&E) DRAP Lahore dated 19-11-2018 for batch # HN180401
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted Stability data along-with HPLC chromatograms and raw data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not available
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The submitted product development and stability study dataof manufacturer is already approved in 320th meeting in Coliate 2MIU Injection case of M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**

721.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 28-05-2021.
	GMP status of the firm	**English Pharmaceutical:** GMP certificate issued based on inspection dated 06-01-2018
	Evidence of approval of manufacturing facility	Firm (M/s English Pharmaceuticals) has submitted copy of renewal of DML letter dated 09-03-2015 specifying Dry powder injectable vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 23532 dated 27-08-2021
	Details of fee submitted	Rs. 75,000/- Dated 12-07-2021
	The proposed proprietary name / brand name	**COLIZONE 4.5MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate sodium …… 4.5MIU
	Pharmacotherapeutic Group of (API)	Antibiotic
	Pharmaceutical form of applied drug	Powder for solution for injection
	Reference to Finished product specifications	USP
	Proposed Pack size	1x1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Colistim injection by Biocare pharmaceuticals
	Name and address of API manufacturer.	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang Hebei Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions**.**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the comparator product Colixin Injection of Pharmis Biofamaceutica
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Shengxue Dacheng Pharmaceutical Co Ltd. No. 50 Shengxue Road Launcheng District Shijiazhuang, Hebei Province, China		
API Lot No.	HN180401		
Description of Pack (Container closure system)	Clear glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 1, 3, 6 (Months)		
Batch No.	Trial 05	Trial 06	
Batch Size	2700 packs	2700 packs	
Manufacturing Date	06-2020	06-2020	
Date of Initiation	15-07-2020	15-07-2020	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. HE20190058) issued by China Food and Drug Administration valid upto 14-08-2024 is submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 8Kg Colistimethate sodium. The invoice is attested by AD (I&E) DRAP Lahore dated 19-11-2018 for batch # HN180401
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted Stability data along-with HPLC chromatograms and raw data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not available

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

Evaluation by PEC:

- The submitted product development and stability study data of manufacturer is already approved in 320th meeting in Coliate 4.5MIU Injection case of M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Review of Colistimethate for Injection along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**

722.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement between contract giver and contract acceptor dated 18-12-2017.
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-10-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 30-10-2019 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22650: 17-08-2021
	Details of fee submitted	PKR 50,000/-: 26-07-2021 + PKR 25,000/-: 10-06-2021
	The proposed proprietary name / brand name	**ROXET CR 12.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric, film-coated, controlled-release tablet contains: Paroxetine (as hydrochloride)…..12.5mg
	Pharmaceutical form of applied drug	Green color, round, biconvex enteric coated tablets, plain from both sides
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s, 20’s, 30’s, 50’s, 100’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paxil CR Tablet **(USFDA** Approved)
	For generic drugs (me-too status)	Paraxyl Tablet by CCL Pharmaceuticals
	Name and address of API manufacturer.	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Seroxat CR 12.5 mg Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.
API Lot No.	5819031201
Description of Pack	Alu-Alu blister

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-126-01	19SB-127-02	19SB-130-03
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	14-08-2019	14-08-2019	14-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. ZJ20180136) issued by China Food and Drug Administration dated 14-11-2018. The certificate is valid till 13-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Paroxetine HCl 1Kg from M/s Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China issued by AD (I&E) DRAP field office. The license was issued on 17-06-2019. • Firm has submitted copy of commercial invoice specifying import of 1Kg Paroxetine HCl. The invoice was signed by AD (I&E) DRAP field office dated 17-06-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

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

Evaluation by PEC[3]:

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in Patrox 12.5mg CR Tablet case of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.
- Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Approved. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

723.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement between contract giver and contract acceptor dated 18-12-2017.
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-10-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 30-10-2019 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22650: 17-08-2021
	Details of fee submitted	PKR 50,000/-: 26-07-2021 + PKR 25,000/-: 10-06-2021
	The proposed proprietary name / brand name	**ROXET CR 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric, film-coated, controlled-release tablet contains: Paroxetine (as hydrochloride)…..25mg
	Pharmaceutical form of applied drug	Pink color, round, biconvex enteric coated tablets, plain from both sides
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s, 20’s, 30’s, 50’s, 100’s

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paxil CR Tablet **(USFDA** Approved)
	For generic drugs (me-too status)	Paraxyl Tablet by CCL Pharmaceuticals
	Name and address of API manufacturer.	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Seroxat CR 25 mg Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.
API Lot No.	5819031201
Description of Pack	Alu-Alu blister

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-131-01	19SB-132-02	19SB-136-03
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	24-08-2019	24-08-2019	24-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. ZJ20180136) issued by China Food and Drug Administration dated 14-11-2018. The certificate is valid till 13-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Paroxetine HCl 1Kg from M/s Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China issued by AD (I&E) DRAP field office. The license was issued on 17-06-2019. • Firm has submitted copy of commercial invoice specifying import of 1Kg Paroxetine HCl. The invoice was signed by AD (I&E) DRAP field office dated 17-06-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

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

Evaluation by PEC[3]:

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in Patrox 25mg CR Tablet case of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.
- Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Approved. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

724.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement between contract giver and contract acceptor dated 18-12-2017.
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-10-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 30-10-2019 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22651: 17-08-2021
	Details of fee submitted	PKR 50,000/-: 26-07-2021 + PKR 25,000/-: 10-06-2021
	The proposed proprietary name / brand name	**ROXET CR 37.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric, film-coated, controlled-release tablet contains: Paroxetine (as hydrochloride).…37.5mg
	Pharmaceutical form of applied drug	Blue color, round, biconvex enteric coated tablets, plain from both sides
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	10's, 20's, 30's, 50's, 100's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paxil CR Tablet **(USFDA** Approved)
	For generic drugs (me-too status)	Paraxyl Tablet by CCL Pharmaceuticals
	Name and address of API manufacturer.	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Seroxat CR 37.5 mg Tablet.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.
API Lot No.	5819031201
Description of Pack	Alu-Alu blister

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-137-01	19SB-138-02	19SB-139-03
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	06-09-2019	06-09-2019	06-09-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. ZJ20180136) issued by China Food and Drug Administration dated 14-11-2018. The certificate is valid till 13-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Paroxetine HCl 1Kg from M/s Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China issued by AD (I&E) DRAP field office. The license was issued on 17-06-2019. • Firm has submitted copy of commercial invoice specifying import of 1Kg Paroxetine HCl. The invoice was signed by AD (I&E) DRAP field office dated 17-06-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

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

Evaluation by PEC[3]:

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in Patrox 37.5mg CR Tablet case of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.
- Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Approved. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

725.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement between contract giver and contract acceptor dated 18-12-2017.
	GMP status of the firm	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-10-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 30-10-2019 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22648: 17-08-2021
	Details of fee submitted	PKR 50,000/-: 26-07-2021 + PKR 25,000/-: 10-06-2021
	The proposed proprietary name / brand name	**ROXET 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Paroxetine HCl…20mg
	Pharmaceutical form of applied drug	Square shape pink color, biconvex film coated tablet engraved GENIX on one side and plain from other side.
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	10's, 20's, 30's, 50's, 100's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paxil Tablet **(USFDA** Approved)
	For generic drugs (me-too status)	Paraxyl Tablet by CCL Pharmaceuticals
	Name and address of API manufacturer.	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Seroxat 20mg Tablet. Firm has also submitted results of comparative dissolution profile of their product against Seroxat 20mg Tablet in three dissolution medium.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China.		
API Lot No.	5819031201		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-140-01	19SB-141-02	19SB-142-03
Batch Size	2000 Tablet	2000 Tablet	2000 Tablet
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	02-09-2019	02-09-2019	02-09-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following observations were reported in the report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. • Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. ZJ20180136) issued by China Food and Drug Administration dated 14-11-2018. The certificate is valid till 13-11-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Paroxetine HCl 1Kg from M/s Zhejiang Haisen Pharmaceutical Co Ltd. Liushi Street, Dongyang city, Zhejiang Province China issued by AD (I&E) DRAP field office. The license was issued on 17-06-2019. • Firm has submitted copy of commercial invoice specifying import of 1Kg Paroxetine HCl. The

		invoice was signed by AD (I&E) DRAP field office dated 17-06-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in Patrox 20mg Tablet case of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.
- Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Approved. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

726.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm is inspected on 02-07-2020 wherein the firm was found to be operating at good level of GMP compliance.
	Evidence of approval of manufacturing facility	The firm has provided Sachet (General) section from confirmed from approved layout plan from licensing division.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16758: 16-06-2021
	Details of fee submitted	PKR 50,000/-: 08-04-2021
	The proposed proprietary name / brand name	**POLYCOL** Jar 578g Powder for Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Polyethylene glycol 3350…….17g
	Pharmaceutical form of applied drug	White to off white color powder filled in HDPE bottle.
	Pharmacotherapeutic Group of (API)	Osmotic laxative

	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	1's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	Miralax for oral solution of M/s Bayer Healthcare LLC (USFDA Approved, over the counter)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai–400 062 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has performed pharmaceutical equivalence and comparative dissolution profile of

		Movcol 578g Jar (B#19SB-149-01) and Miralax 578g Jar (B # TN00RM) of M/s Bayer. Quality tests of both products including description, identification, filled weight, moisture content and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra India.		
API Lot No.	AP0919009		
Description of Pack (Container closure system)	HDPE Bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-149-01	19SB-150-02	19SB-151-03
Batch Size	50 Bottles	50 Bottles	50 Bottles
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	09-09-2019	09-09-2019	09-09-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s. Avesta Pharma Pvt. Ltd, Maharashtra state, India issued by Food and Drug Administration, Maharashtra state, India. It is valid upto 15-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software from Waters Corporation. Audit trail of testing of product has not been submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.
- Scientific justification of using Jar container closure system instead of using foil pouch as per reference product i.e., Miralax of M/s Bayer for achieving unit dose dispensing of applied product.
- Evidence of availability of drug product in applied container closure system in reference regulatory authorities.
- Submit product development and stability study data of commercial batches manufactured by the drug product manufacturer, since the submitted data are of trial batches.

Decision: Deferred for following submissions:

- **Confirmation of required facility where manufacturing and packaging in Jar can be carried out.**
- **Clarification how the applied product is similar in terms of packaging material, unit dose and total dose per pack in comparison with the innovator's product.**
- **Evidence of HPLC system along with RI detector which is used for product testing.**
- **Submission of 25,000/- differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Valid contract manufacturing agreement between the contract giver and contract acceptor.**

727.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd, 44-45-B, Korangi Creek Road, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm is inspected on 02-07-2020 wherein the firm was found to be operating at good level of GMP compliance.
	Evidence of approval of manufacturing facility	The firm has provided Sachet (General) section from confirmed from approved layout plan from licensing division.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16758: 16-06-2021
	Details of fee submitted	PKR 50,000/-: 08-04-2021
	The proposed proprietary name / brand name	**POLYCOL Jar 238g Powder for Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains: Polyethylene glycol 3350…….17g
	Pharmaceutical form of applied drug	White to off white color powder filled in HDPE bottle.
	Pharmacotherapeutic Group of (API)	Osmotic laxative
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	1's
	Proposed unit price	As per PRC

	The status in reference regulatory authorities	Miralax for oral solution of M/s Bayer Healthcare LLC (USFDA Approved, over the counter)
	For generic drugs (me-too status)	Not available
	Name and address of API manufacturer.	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has performed pharmaceutical equivalence of Movcol 238g Jar (B#19SB-143-01) of M/s Genix pharma with Miralax 238g Jar (B # 0C20PU) of M/s Bayer. Quality tests of both products including description, identification,

		filled weight, moisture content and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Avesta Pharma Pvt Ltd., Shivam chambers, 106/108, First Floor, S.V. Road, Goregaon west, Mumbai – 400 062 Maharashtra India.		
API Lot No.	AP0919009		
Description of Pack (Container closure system)	HDPE Bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-143-01	19SB-144-02	19SB-145-03
Batch Size	50 Bottles	50 Bottles	50 Bottles
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	09-09-2019	09-09-2019	09-09-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s. Avesta Pharma PVT LTD, Maharashtra state, India issued by Food and Drug Administration, Maharashtra state, India. It is valid upto 15-09-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of polyethylene glycol-3350 (5000Kg, Batch # AP0919009) attested by AD (I & E) DRAP, Karachi dated 18-04-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software from Waters Corporation. Audit trail of testing of product has not been submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.

- Scientific justification of using Jar container closure system instead of using foil pouch as per reference product i.e., Miralax of M/s Bayer for achieving unit dose dispensing of applied product.
- Evidence of availability of drug product in applied container closure system in reference regulatory authorities.
- Submit product development and stability study data of commercial batches manufactured by the drug product manufacturer, since the submitted data are of trial batches.

Decision: Deferred for following submissions:

- **Confirmation of required facility where manufacturing and packaging in Jar can be carried out.**
- **Clarification how the applied product is similar in terms of packaging material, unit dose and total dose per pack in comparison with the innovator's product.**
- **Evidence of HPLC system along with RI detector which is used for product testing.**
- **Submission of 25,000/- differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Valid contract manufacturing agreement between the contract giver and contract acceptor.**

728.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cherwel Pharmaceuticals (Pvt) Ltd. Plot # 20, Phase 4, Hattar Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 21-04-2017 is submitted
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7212: 04-03-2021
	Details of fee submitted	PKR 50,000/-: 24-02-2021
	The proposed proprietary name / brand name	**IMIPEN Injection 250mg IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as monohydrate…250mg Cilastatin as sodium…250mg
	Pharmaceutical form of applied drug	Glass vial filled with white to pale yellow powder along with 10ml ampoule of 0.9% NaCl solution.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Impenem and cilastatin Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Cilapen Injection by Bosch Pharma

	Name and address of API manufacturer.	Sun Pharmaceutical Industries Ltd. Industrial Area 3, Dewas, 455001, Madhiya Paradesh India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Cilapen 250mg Injection (IV) of Bosch Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance and the drug product product.

STABILITY STUDY DATA

Manufacturer of API	Sun Pharmaceutical Industries Ltd. Industrial Area 3, Dewas, 455001, Madhiya Paradesh India.
API Lot No.	AB06444
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CI-001	CI-002	CI-003
Batch Size	350 vials	350 vials	350 vials
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	07-01-2020	07-01-2020	07-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. V/WHOGMP/Rev./Sun-17/2019/5115) issued by Office of the Drugs Controller, Food & Drug Administration Madhya Pradesh dated 3-10-2019. The certificate is valid till 02-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Imipenem / Cilastatin 2Kg from M/s Sun Pharmaceuticals India issued by AD (I&E) DRAP field office. The license was issued on 16-01-2020. • Firm has submitted copy of commercial invoice dated 16-01-2020 specifying import of 2Kg Imipenem/cilastatin. The invoice is signed by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in XONEM Injection 250mg IV case of M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
- Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Approved.

- **M/s Bio-Next Pharmaceuticals shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent along with BMR of recently manufactured batches from M/s Bio-Next Pharmaceuticals, as evidence of use of the recommended diluent before issuance of Registration letter.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit Pharmaceutical equivalence studies against the innovator product before issaunce of registration letter.**

• **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio-Next Pharmaceuticals.**		
729.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cherwel Pharmaceuticals (Pvt) Ltd. Plot # 20, Phase 4, Hattar Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 21-04-2017 is submitted
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7213: 04-03-2021
	Details of fee submitted	PKR 50,000/-: 24-02-2021
	The proposed proprietary name / brand name	**IMIPEN Injection 500mg IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem as monohydrate…500mg Cilastatin as sodium…500mg
	Pharmaceutical form of applied drug	Glass vial filled with white t pale yellow powder along with ampoule of 0.9% NaCl solution.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Impenem and cilastatin Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Cilapen Injection by Bosch Pharma
	Name and address of API manufacturer.	Sun Pharmaceutical Industries Ltd. Industrial Area 3, Dewas, 455001, Madhiya Paradesh India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Cilapen 500mg Injection (IV) of Bosch Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance and the drug product product.

STABILITY STUDY DATA

Manufacturer of API	Sun Pharmaceutical Industries Ltd. Industrial Area 3, Dewas, 455001, Madhiya Paradesh India.		
API Lot No.	AB06444		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CI-004	CI-005	CI-006
Batch Size	350 vials	350 vials	350 vials
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	07-01-2020	07-01-2020	07-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. V/WHOGMP/Rev./Sun-17/2019/5115) issued by Office of the Drugs Controller, Food & Drug Administration Madhya Pradesh dated 3-10-2019. The certificate is valid till 02-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Imipenem / Cilastatin 2Kg from M/s Sun Pharmaceuticals India issued by AD (I&E) DRAP field office. The license was issued on 16-01-2020. • Firm has submitted copy of commercial invoice dated 16-01-2020 specifying import of 2Kg Imipenem/cilastatin. The invoice is signed by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in XONEM Injection 500mg IV case of M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
- Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer.

Decision: Decision: Approved.

- **M/s Bio-Next Pharmaceuticals shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent along with BMR of recently manufactured batches from M/s Bio-Next Pharmaceuticals, as evidence of use of the recommended diluent before issuance of Registration letter.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit Pharmaceutical equivalence studies against the innovator product before issaunce of registration letter.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio-Next Pharmaceuticals.**

b. Deferred cases of local manufacturing

730.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7 Jail Road Quetta.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 01-02-2021 is submitted
	GMP status of the firm	The Firm has submitted copy of GMP certificate based on evaluation conducted on 07-05-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section dated 27th October, 2020 specifying Dry Powder Inhaler Capsule (General)- New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16029: 09-06-2021
	Details of fee submitted	PKR 50,000/-: 19-03-2021+ PKR 25,000/-: 15-06-2021
	The proposed proprietary name / brand name	**BI HALER DPI Capsule 200mcg / 6mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Budesonide.....200mcg Formoterol fumarate dihydrate.....6mcg Each delivered dose (the dose that leaves the mouthpiece) contains Budesonide 160 mcg / inhalation and Formoterol fumarate dihydrate 4.5 mcg / inhalation.
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Drugs for obstructive airway diseases: Adrenergics, Inhalants. ATC code: R03AK07
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	"SYMBICORT TURBOHALER 200/6mcg INHALATION POWDER" by AstraZeneca UK Limited (MHRA approved)
	For generic drugs (me-too status)	Formiget 200mcg + 6mcg DPI capsule of M/s Getz Pharma (Reg # 085999)
	Name and address of API manufacturer.	**Budesonide:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA **Formoterol fumarate dihydrate:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 60 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their formulation with innovator product Symbicort Turbohaler of M/s Astrazeneca and performed tests of Aerodynamic particle size distribution (APSD) & Delivered dose uniformity (DDU) of both capsules.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of analytical method validation of drug product.

STABILITY STUDY DATA

Manufacturer of API	**Budesonide:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA **Formoterol fumarate dihydrate:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA.
API Lot No.	Budesonide: BD-18401 Formoterol fumarate dihydrate: FF-19001
Description of Pack (Container closure system)	Alu Alu Blister pack, 30's
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,3,6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-892-L	NPD-C-893-P	NPD-C-894-P
Batch Size	6000 capsules	6000 capsules	6000 capsules
Manufacturing Date	02-12-2019	02-12-2019	02-12-2019
Date of Initiation	06-12-2019	06-12-2019	06-12-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Aarti Industries Ltd., District Palghar – 401 506, Maharashtra, INDIA issued by Food and Drugs Administration (Maharashtra State), India. It is valid till 09-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Budesonide: Firm has submitted copy of invoice specifying purchase of 40g of Budesonide (micronised) attested by AD I & E Karachi dated 07-08-2019. Formoterol Fumarate Dihydrate: Firm has submitted copy of invoice specifying purchase of 15g of Formoterol Fumarate Dihydrate (micronised) attested by AD I & E Karachi dated 19-08-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software 21 CFR and copies of audit trail on testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has responded that they have already submitted differential fee PKR 25,000/- dated 15-06-2021 vide slip number 087907483660.
Submit valid contract manufacturing agreement between the contract giver and contract acceptor.	Firm has submitted copy of contract manufacturing agreement dated 01-02-2021 between the contract giver and contract acceptor.
Submit product development and stability study data of commercial batches manufactured by the drug product manufacturer, since the submitted data are of trial batches.	Firm has submitted 6 months stability study data of trial batches. Firm has also submitted stability data sheets for 3 months stability testing of three commercial batches with following details: **Batch No: P07381** Batch size: 13000 packs; Mfg date: 07-2021; Stability initiation date: 11-08-2021; API lot number: 2104000065 2104000146

Batch No: P07388

Batch size	Mfg date	Stability initiation date	API lot number
8659 packs	07-2021	12-08-2021	2104000065 2104000146

Batch No: P07627

Batch size	Mfg date	Stability initiation date	API lot number
13000 packs	11-2021	30-11-2021	2104000065 2104000146

However, firm has not submitted complete stability study data of 3 commercial batches along with requisite documents as per CTD guidance document.

Decision of 316th meeting of Registration Board:

Deferred for submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Submission by the firm:

Firm has submitted complete stability data of commercial batches for which initial detail was provided in 316th meeting.

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in TYCORT 200mcg + 6mcg DPI Capsule case of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan.
- Registration Board in its 321st meeting also decided as "*Registration Board deliberated the matter in detail and decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer"*
-

The dry powder inhaler capsule is intended to be marketed along with Dry Powder Inhaler Device of following description:
Name: DPI Device
Model no. BDD07
Capsule size: 3 # Capsule
Manufacturer: Shanghai Huarui Aerosol Co., Ltd,
No.222, Yuanchun Road, Pudong New Area,
Shanghai, china.
Shelf life: 3 years

Decision: Approved. The firm shall submit fee of Rs. 75,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**
- **Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter:**

"**Name: DPI Device**
Model no. BDD07
Capsule size: 3 # Capsule
Manufacturer: Shanghai Huarui Aerosol Co., Ltd,
No.222, Yuanchun Road, Pudong New Area,
Shanghai, china.
Shelf life: 3 years"

- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan**

731.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7 Jail Road Quetta.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 01-02-2021 is submitted
	GMP status of the firm	The Firm has submitted copy of GMP certificate based on evaluation conducted on 07-05-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section dated 27th October, 2020 specifying Dry Powder Inhaler Capsule (General)- New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16024: 09-06-2021
	Details of fee submitted	PKR 50,000/-: 19-03-2021+ PKR 25,000/-: 15-06-2021
	The proposed proprietary name / brand name	**BI HALER DPI Capsule 400mcg / 12mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Budesonide.....400mcg Formoterol fumarate dihydrate.....12mcg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Drugs for obstructive airway diseases: Adrenergics, Inhalants. ATC code: R03AK07
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	"SYMBICORT TUBOHALER 400/12mcg INHALATION POWDER" by AstraZeneca UK Limited (MHRA approved)
	For generic drugs (me-too status)	Formiget 400mcg + 12mcg DPI capsule of M/s Getz Pharma (Reg # 098723)
	Name and address of API manufacturer.	**Budesonide:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA **Formoterol fumarate dihydrate:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 60 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their formulation with innovator product Symbicort Turbohaler of M/s Astrazeneca and performed tests of Aerodynamic particle size distribution (APSD) & Delivered dose uniformity (DDU) of both capsules.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of analytical method validation of drug product.

STABILITY STUDY DATA

Manufacturer of API	**Budesonide:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA **Formoterol fumarate dihydrate:** M/s Aarti Industries Ltd., Unit-IV, Plot No E – 50, MIDC, Tarapur, Taluka & District Palghar – 401 506, Maharashtra, INDIA.
API Lot No.	Budesonide: BD-18401 Formoterol fumarate dihydrate: FF-19001
Description of Pack (Container closure system)	Alu Alu Blister pack, 30's
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0,3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-877-L	NPD-C-878-P	NPD-C-879-P
Batch Size	6000 capsules	6000 capsules	6000 capsules
Manufacturing Date	11-2019	11-2019	11-2019
Date of Initiation	06-12-2019	06-12-2019	06-12-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Aarti Industries Ltd., District Palghar – 401 506, Maharashtra, INDIA issued by Food and Drugs Administration (Maharashtra State), India. It is valid till 09-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Budesonide: Firm has submitted copy of invoice specifying purchase of 40g of Budesonide (micronised) attested by AD I & E Karachi dated 07-08-2019. Formoterol Fumarate Dihydrate: Firm has submitted copy of invoice specifying purchase of 15g of Formoterol Fumarate Dihydrate (micronised) attested by AD I & E Karachi dated 19-08-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software 21 CFR and copies of audit trail on testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has responded that they have already submitted differential fee PKR 25,000/- dated 15-06-2021 vide slip number 03522882089.
Submit valid contract manufacturing agreement between the contract giver and contract acceptor.	Firm has submitted copy of contract manufacturing agreement dated 01-02-2021 between the contract giver and contract acceptor.
Submit product development and stability study data of commercial batches manufactured by the drug product manufacturer, since the submitted data are of trial batches.	Firm has submitted 6 months stability study data of trial batches. Firm has also submitted stability data sheets for 3 months stability testing of three commercial batches with following details: **Batch No: P07404** Batch size: 10333 packs; Mfg date: 08-2021; Stability initiation date: 16-08-2021; API lot number: 2104000065 2104000146

Batch No: P07408

Batch size	Mfg date	Stability initiation date	API lot number
13000 packs	08-2021	23-08-2021	2104000065 2104000146

Batch No: P07438

Batch size	Mfg date	Stability initiation date	API lot number
13000 packs	08-2021	03-09-2021	2104000065 2104000146

However, firm has not submitted complete stability study data of 3 commercial batches along with requisite documents as per CTD guidance document.

Decision of 316th meeting of Registration Board:

Deferred for submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Submission by the firm:

Firm has submitted complete stability data of commercial batches for which initial detail was provided in 316th meeting.

- The submitted product development and stability study data of manufacturer is already approved in 297th meeting in TYCORT 400mcg + 12mcg DPI Capsule case of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan.

Registration Board in its 321st meeting also decided as "*Registration Board deliberated the matter in detail and decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer"*

Decision: Approved. The firm shall submit fee of Rs. 75,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**
- **Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter:**

"**Name: DPI Device**
Model no. BDD07
Capsule size: 3 # Capsule
Manufacturer: Shanghai Huarui Aerosol Co., Ltd,
No.222, Yuanchun Road, Pudong New Area,
Shanghai, china.

- **Shelf life: 3 years".**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan**

732.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7 Jail Road Quetta.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Contract manufacturing agreement dated 01-02-2021 is submitted

	GMP status of the firm	The Firm has submitted copy of GMP certificate based on evaluation conducted on 07-05-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section dated 27th October, 2020 specifying Dry Powder Inhaler Capsule (General)- New.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16009: 09-06-2021
	Details of fee submitted	PKR 50,000/-: 05-04-2021 + PKR 25,000/-: 15-06-2021
	The proposed proprietary name / brand name	**TIO HALER DPI Capsule 18 mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: 22.5mcg of Tiotropium bromide monohydrate eq. to Tiotropium……..18mcg The delivered dose (the dose that leaves the mouthpiece) is 10.4 mcg Tiotropium.
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Anticholinergic agents
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Spiriva 18 mcg capsule (**USFDA** approved)
	For generic drugs (me-too status)	Gentrop 18 mcg Rotacaps of Genix Pharma (Reg#086941)
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd. Address A-14/15, MIDC area, Chincholi, Solapur-413255, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 6 months accelerated and 60 months real time data of 3 batches of API.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their formulation with innovator product Spiriva 18mcg DPI Capsule of M/s Boehringer Ingelheim and performed tests of Aerodynamic particle size distribution (APSD) & Delivered dose uniformity (DDU) of both capsules.
	Analytical method validation/verification of product	Firm has submitted protocols and reports of analytical method validation of drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vamsi Labs Ltd., Address A-14/15, MIDC area, Chincholi, Solapur-413255, Maharashtra, India		
API Lot No.	TBM0090619		
Description of Pack (Container closure system)	Alu Alu Blister pack, 30's		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-885-L	NPD-C-886-P	NPD-C-887-P
Batch Size	6000 capsules	6000 capsules	6000 capsules
Manufacturing Date	27-11-2019	27-11-2019	27-11-2019
Date of Initiation	06-12-2019	06-12-2019	06-12-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Vamsi Labs Ltd., India issued by Food and Drugs Administration (Maharashtra State), India. It is valid till

		19-05-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying purchase of 20g of Tiotropium Bromide Monohydrate (micronised) attested by AD I & E Karachi dated 02-11-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software 21 CFR and copies of audit trail on testing of drug product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has responded that they have already submitted differential fee PKR 25,000/- dated 15-06-2021 vide slip number 7815511710.
Submit valid contract manufacturing agreement between the contract giver and contract acceptor.	Firm has submitted copy of contract manufacturing agreement dated 01-02-2021 between the contract giver and contract acceptor.
Submit product development and stability study data of commercial batches manufactured by the drug product manufacturer, since the submitted data are of trial batches.	Firm has submitted 6 months stability study data of trial batches. Firm has also submitted stability data sheets for 3 months stability testing of three commercial batches with following details: **Batch No: P07380** Batch size: 12333 packs; Mfg date: 07-2021; Stability initiation date: 04-08-2021; API lot number: 2103000010 **Batch No: P07387** Batch size: 9333 packs; Mfg date: 08-2021; Stability initiation date: 27-08-2021; API lot number: 2103000010 **Batch No: P07456** Batch size: 12466 packs; Mfg date: 09-2021; Stability initiation date: 16-09-2021; API lot number: 2103000010 However, firm has not submitted complete stability study data of 3 commercial batches along with requisite documents as per CTD guidance document.

Decision of 316th meeting of Registration Board:

Deferred for submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Submission by the firm:

Firm has submitted complete stability data of commercial batches for which initial detail was provided in 316th meeting. • The submitted product development and stability study data of manufacturer is already approved in 297th meeting in Tiohale DPI Capsule 18 mcg case of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan. Registration Board in its 321st meeting also decided as "*Registration Board deliberated the matter in detail and decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer"*
Decision: Approved. The firm shall submit fee of Rs. 75,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application** • **Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter:** "**Name: DPI Device** **Model no. BDD07** **Capsule size: 3 # Capsule** **Manufacturer: Shanghai Huarui Aerosol Co., Ltd,** **No.222, Yuanchun Road, Pudong New Area,** **Shanghai, china.** • **Shelf life: 3 years".** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan**

733.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swiss Pharmaceuticals Pvt Ltd A/159, SITE-II Super Highway Karachi.**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 29-05-2020 is submitted.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-03-2022 based on inspection dated 11-02-2019. As per the certificate, it was valid till 09-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML of M/s Vision Pharmaceuticals DML No 000517 dated 07-06-2021 specifying sterile dry powder injectable vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 20655: 29-07-2021
	Details of fee submitted	PKR 50,000/-: 22-12-2020
	The proposed proprietary name / brand name	**PTONIX 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Pantoprazole (as sodium)……40mg
	Pharmaceutical form of applied drug	White or almost white colored lyophilized powder
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	BP specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Protonix IV 40mg **(USFDA** Approved)
	For generic drugs (me-too status)	Zopent Injection by Hilton
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.

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

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	2008902		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	2009714	2009715	2009716
Batch Size	16,800 Vials	16,800 Vials	16,800 Vials
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	08-10-2020	08-10-2020	08-10-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate dated 31-07-2019 of M/s Vision Pharmaceuticals (DML No. 000806 semi basic) issued based on inspection dated 11-02-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted inventory transfer note from SAP of the firm dated 08-10-2020 for the same batch.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.

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

Evaluation by PEC:

The application of the firm for contract manufacturing from M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad was not submitted as per the guidance document approved by Registration Board. The submitted application was in variation to the guidance document for various modules, sections and sub sections majorly including complete module 1, section 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.4, 3.2.S.5, 3.2.P.2.2.1, 3.2.P.2.6, 3.2.P.3.5, 3.2.P.5.1, 3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.4, 3.2.P.6 and 3.2.P.8. Furthermore, it is also pertinent to mention that the drug product manufacturer has submitted COA of drug substance which is released on 26-02-2018 and provided batch release certificates of 3 batches of drug product released on 09-2017 instead of submitting data of same batches as per the guidance document. Therefore, the firm was advised to resubmit the application compiled in the light of the guidance document approved by Registration Board so that further evaluation of your application could be carried out.

In response, the firm has changed drug product specifications from in house to BP without submission of fee. Firm has also changed the drug substanbce source from Everest Organics Limited Aroor Village Sadasivapet Mandal Sangareddy District Aroor (V), Sadasivpet(M), Sangareddy District Telangana India to M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.

The response was also evaluated, and the found deficient for various points. The following points were communicated to the firm.

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of the applied product in line with innovator product / reference product along with submission of requisite fee.	Firm has submitted following label claim without submission of fee. Each vial Contains: Pantoprazole (as sodium)……40mg
2.	In your initial submission, you have mentioned in house specifications for the drug product, while in the later submission you have mentioned BP specifications. Justification is required in this regard along with evidence when you have changed the specifications of your already registered product.	In our previous submission the testing for 3 batches was done on UV, but parallel we change our Standard Analytical Procedure and shift our testing method to HPLC. Firm has submitted Revised testing method which was signed and issued on 31-12-2021. This method contains HPLC test for assay of drug product, however, for bulk stage the assay method was based on UV. As per Documents, firm has changed assay to HPLC method on 31-12-2021 while the stability data was initiated on October 2020. Furthermore, firm could not provide any evidence of intimation to DRAP regarding revision of the specifications of their already registered product from in house to BP specs.

3.	In your initial application you have specified that the source of drug substance is Everest Organics Limited Aroor Village Sadasivapet Mandal Sangareddy District Aroor (V), Sadasivpet(M), Sangareddy District Telangana India, while in new submission you have changed the source to M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad. Justification is required in this regard along with submission of requisite fee.	As we have two DMLs one for finished drugs and secod for semi basic dosage forms. The lyophilized pantoprazole is always procured from M/s Vision Pharmaceuticals but the powder pantoprazole for lyophilization is procured from Everest organics limited.
4.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted standard testing method of pantoprazole sodium sesquihydrate drug substance from Vision Pharmaceuticals dated 29-12-2021. The submitted document does not specify whether it is of semi basic DML or of DML issued by way of formulation. Moreover the specifications are issued on December 2021 while stability batches were manufactured in October 2020.
5.	Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	Firm has submitted verification studies dated 05-09-2020 based on HPLC method, while as per the submitted specifications of the drug substance, the assay method is based on potentiometric titration.
6.	The COA of drug substance manufacturer specifies that the material was released on 31-09-2020 while the drug product manufacturer has sampled the product on 02-09-2020 and released on 16-09-2020. Justification is required in this regard.	Firm submitted that it was a typo error. Firm has submitted another copy of COA of the same batch. In the newly submitted COA from Vision Pharmaceuticals (Semi-Basic DML) the batch was released on 31-08-2020 as per In-house specification and assay on UV method. While as per the raw material analysis report from Vision Pharmaceuticals (Formulation DML), the batch was released on 16-09-2020 as per Innovator's specification and assay on UV method. The drug substance specifications, BP monograph and submitted COA are contradictory.
7.	Justify the use of 10ml water for injection as diluent since the innovator product recommends that the product should be reconstituted with 10ml 0.9% sodium chloride solution.	Firm has submitted that they are using 10ml of 0.9% sodium chloride solution as diluent. However previously the firm has specified water for injection as the diluent.

8.	Submit results of compatibility studies in section 3.2.P.2.6.	Firm has not submitted compatabiity study report instead only submitted a batch release report.
9.	The analytical method and specifications of the drug product has been generated and signed on 31-12-2021 with a dsscription "this is a new document on this subject" while the stability batches were manufactured in September 2020. Justify how the submitted specifications could be considered applicable for testing of these batches.	The provided analytical method and specifications of drug product has been submitted is the updated one, replacing the old version. As per Documents, firm has changed assay to HPLC method on 31-12-2021 while the stability data was initiated on October 2020. Furthermore, firm could not provide any evidence of intimation to DRAP regarding revision of the specifications of their already registered product from in house to BP specs.
10.	Analytical method alidation studies of the drug product were developed in 2017 wherein the specifications and analytical method of BP 2020 were claimed. Justify how validation of analytical method of 2020 can be performed in 2017.	Firm has once again submitted same old verification studies of 2017 in which the assay method was different from that specified in the latest specifications of the firm as well as BP monograph.
11.	Justify how three batches of drug product with BP specs were released on 05-10-2020 while the drug specifications are different from that specified in BP monograph and are exactly same as that submitted in initial application as in-house specifications.	It was a typo error, updated range was according to BP.
12.	Submit evidence of procurement of the drug substance.	Firm has submitted inventory transfer note from SAP of the firm dated 08-10-2020 for the same batch. However, the document does not specify any quantity. Moreover, the document for transfer of inventory is of 08-10-2020, while as per the raw material analysis report from Vision Pharmaceuticals (Formulation DML), the batch was released on 16-09-2020.
13.	Justify how the manufacturing of commercial batches were carried out from 17-09-2020 while the drug substance used in those batches was released on 31-09-2020.	The drug substance was released on 07-09-2020. However as per invoice the material was transferred on 08-10-2020, and as per raw material analysis report the material was released on 16-09-2020.

Decision of 320th meeting of Registration Board:

Deferred for following:

- Submission of applicable fee for revision of source of drug substance, revision of specifications and label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Scientific justification how a revised HPLC method dated 31-12-2021 can represent the results of the stability studies which were initiated in October 2020.
- Approval of DRAP for change in specifications of the registered product for which stability data is submitted.

- Scientific justification for performing verification studies of analytical method of drug substance dated 05-09-2020 based on HPLC method, while as per the submitted specifications of the drug substance, the assay method is based on potentiometric titration.
- Scientific justification for having drug substance specifications which are different from the specifications of drug substance manufacturer as well as BP monograph.
- Clarification about the use of 10ml water for injection as diluent for the applied product since the innovator product recommends different diluent.
- Verification studies of the analytical method of drug product.
- Evidence of procurement of the drug substance.
- Scientific justification for manufacturing and testing commercial batches of a registered drug product on non-pharmacopoeial specifications while BP monograph was already available for the drug product.

Submission by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of applicable fee for revision of source of drug substance, revision of specifications and label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has not submitted any fee.
2.	Scientific justification how a revised HPLC method dated 31-12-2021 can represent the results of the stability studies which were initiated in October 2020.	Change specification granted from DRAP in May 2021, after that testing specification change to BP from vision specification. Testing method also revised after grant of this permission from DRAP.
3.	Approval of DRAP for change in specifications of the registered product for which stability data is submitted.	Firm has submitted one page which shows that specifications of Fitral 40mg Injection is changed from inhouse to BP Specs. However, the letter do not contain first page which shows date of the
4.	Scientific justification for performing verification studies of analytical method of drug substance dated 05-09-2020 based on HPLC method, while as per the submitted specifications of the drug substance, the assay method is based on potentiometric titration.	Raw material once received is Lyophilized by Vision Semi Basic Plant and that Lyophilized ready to fill powder is then filled in vials. So, Method verification/validation of that Lyophilized material is performed by HPLC which is according to BP method, and that material is filled in Vials. The titration method is just mentioned for Pantoprazole sodium sesquihydrate Raw material, not for Lyophilized material.
5.	Scientific justification for having drug substance specifications which are different from the specifications of drug substance manufacturer as well as BP monograph.	Pantoprazole sodium (Lyophilized) is present in BP Monograph and we are following BP Specs.
6.	Clarification about the use of 10ml water for injection as diluent for the applied product since the innovator product recommends different diluent.	Normal saline 10ml under registration with DRAP, water for injection only use to solubilized the material and this 10ml solution transfer to 100ml Normal saline infusion.
7.	Verification studies of the analytical method of drug product.	Verification studies of drug product are provided by the firm.

8.	Evidence of procurement of the drug substance.	Firm has submitted inventory transfer note from SAP of the firm dated 06-07-2020 for batch008902.
9.	Scientific justification for manufacturing and testing commercial batches of a registered drug product on non-pharmacopoeial specifications while BP monograph was already available for the drug product.	Change specification granted from DRAP in May 2021, after that testing specification change to BP from vision specification. Testing method also revised after grant of this permission from DRAP

Decision: Deferred for following:

- **Review of manufacturing requirement of the applied product as per innovator drug product or reference regulatory authority, whether lyophilized or otherwise.**
- **details of already registered drug products with available manufacturing facilities**

734.	Name, address of Applicant / Marketing Authorization Holder	M/s Swiss Pharmaceuticals (Pvt) Ltd. A/159, SITE, Super Highway Karachi.
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 29-05-2020 is submitted.
	GMP status of the firm	**Swiss Pharmaceuticals:** 18-10-2018: GMP compliance level is rated as GOOD." **Global pharmaceuticals:** 11 & 24-10-2018: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 18-12-2017 specifying reallocation of dry powder injection (carbapenem) section in place of withdrawn Biotech section (BSF)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1847: 14-01-2021
	Details of fee submitted	PKR 50,000/-: 07-01-2021
	Proposed proprietary name / brand name	CILSNIM 500mg Injection IV
	Strength/ concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem (as monohydrate).……500mg Cilastatin (as sodium)……500mg
	Pharmaceutical form of applied drug	White to pale yellow powder filled in clear glass vials with grey rubber stopper and blue color flip off seal
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic

	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	Status in reference regulatory authorities	Primaxin Injection (USFDA Approved)
	For generic drugs (me-too status)	Onem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai City Guangdong Province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Primaxin Injection IV of Merck & Co.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai City Guangdong Province China
API Lot No.	3951902009 3951903005
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19G096	19G097	19G098
Batch Size	9041 vials	9041 vials	9041 vials
Manufacturing Date	07-2019	07-2019	07-2019
Date of Initiation	07-08-2019	07-08-2019	23-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: • The HPLC software is 21 CFR compliant. • The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20180909) issued by China Food and Drugs Administration. The certificate is valid till 12-05-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**3951902009:** Firm has submitted copy of commercial invoice cleared dated 27-06-2019 specifying import of 50Kg imipenem and cilastatin for injection. The commercial invoice is attested by AD (I&E) DRAP field office. **3951903005:** No evidence of import is submitted for this batch.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Provide correct label claim as per the innovator / reference product in section 1.5.2 along with submission of requisite fee, since the submitted label claim is not as per reference product.	Firm has revised the label claim as per the reference product without submission of fee.
Justify your drug substance without sodium bicarbonate since USP as well as reference product specifies that sodium bicarbonate is present in the finished drug product.	Firm has submitted that the drug substance contains sodium bicarbonate. Firm has also submitted COA of drug substance which specify sodium bicarbonate.
Provide data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the	Firm has submitted that we have performed method verification for drug product and we are using the same testing method for the drug substance therefore we did not perform verification studies of the drug substance.

Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was carried out without performing verification studies.	
Submit CoA of reference standard used in the testing of drug substance in section 3.2.S.5.	Firm has submitted USP certificate of reference standard for imipenem as well as cilastatin.However the method of analysis submitted by the firm specify that they are not using this reference standard.
Justify how 1106mg drug substance is equivalent to 500mg of imipenem and 500mg cilastatin along with sodium bicarbonate.	Firm has not submitted any justification against this observation
Justify the use of 10ml WFI as a diluent along with applied product. Since this diluent is not used by the innovator / reference product.	Firm has submitted that WFI is used for reconstitution of those injectables vials which is injected through IV. Innovator mentioned on label of the vials that after suspension, vial contents transferred to 100ml of infusion solution and does not describe the procedure for preparation of the suspension of the vial contents. So based on this fact use of WFI is suitable and justified. Innovator product does not recommend reconstitution with WFI
Justify why the pharmaceutical equivalence study does not include all critical steps as mentioned in USP monograph.	As per WHO guidelines pharmaceutical equivalence for parenteral drugs is not required but we applied two test for quality and safety of our product that are pH and assay. Firm has not submitted any evidence of such guidelines. Nor they have submitted any scientific justification for skipping important tests.
Provide data in section 3.2.P.2.6 as per the guidance document approved by Registration Board which specifies that "Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product."	Firm has submitted that Innovator mentioned on label of the vials that after suspension, vial contents transferred to 100ml of infusion solution and does not describe the procedure for preparation of the suspension of the vial contents and particular diluent. WFI is used for reconstitution of those injectables vials which is injected through IV so based on this fact we used WFI as diluent. Firm has not submitted compatibility studies as per the requirement of CTD.
Justify why the test of "constituted solution" and "particulate matter in injection" is not included in your product specification since these tests are recommended by USP.	Firm has submitted that testing method has been revised as per USP. Firm has not submitted any fee for revision of specification and testing method. Moreover the submitted testing method is different from USP monograph in terms of standard preparation, and assay calculation method and formula.
Justify the test of pH in section 3.2.P.5.2 which specifies that reconstitute the sample in 10ml WFI, however USP specifies that reconstitute as directed in the labelling. The labelling of the innovator / reference product does not recommend reconstitution in WFI.	Firm has submitted that Innovator mentioned on label of the vials that after suspension, vial contents transferred to 100ml of infusion solution and does not describe the procedure for preparation of the suspension of the vial contents and particular diluent. WFI is used for reconstitution of those injectables vials which is injected through IV so based on this fact we used WFI as diluent. Firm has not submitted any justification for the observation.
Justify the use of imipenem + cilastatin working standard for the assay since USP has recommended separate standard preparation for imipenem as well as cilastatin for the assay test.	Firm has again submitted separate USP certificate of reference standard for imipenem as well as cilastatin. However the method of analysis submitted by the firm specify that they are not using seprate reference standard.
Justify why the calculation formula used for the assay test is different from that specified in USP monograph.	Firm has submitted that testing method is revised and all required formulas incorporated. However as per the revised testing method the formula is different from that specified in USP monograph.
Clarify the batch size of stability batches, since batch size of 9041 vials is mentioned in stability data sheets, while 4520 vials is mentioned in product batch analysis certificate.	Typographic error. The batch size is 9041 vials.
USP recommends separate injections of imipenem and cilastatin standard preparation, while you have	Firm has submitted that seprate imipenem and cilastatin sodium commercial material is not available with us. We

used same standard preparation containing both drug substances. Justification is required in this regard.	standardized our combined available material with USP reference standard of imipenem and cilatstatin and using it as secondary working standard for routine testing of drug substance and product. Firm has not submitted any scientific justification.
Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
Documents for the procurement of API (Batch number 3951903005) with approval from DRAP.	Not submitted
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted

Decision of 312nd meeting of Registration Board:

Registration Board delibrated the case in detail and observed that the contract manufacturer has not performed complete product development studies, the specifications adopted by the manufacturer throughout stability studies were not according to USP and that the stability batches have also expired.

- Scientific justification for not performing verification studies for analytical method of drug substance.
- Certificate of analysis of reference standard which is actually used in the analysis of drug substance and drug product.
- Scientific justification for using pre-mixed drug substance having both imipenem as well as cilatatin as working standard for analysis of commercial bathes of drug product.
- Scientific justification for having a master formulation containing 1106mg of drug substance in pre-mixed form containing imipenem monohydrate, cilastatin sodium as well as sodium bicarbonate which is equivalent to 500mg imipenem and 500mg cilastatin.
- Scientific justification for using water for injection as a diluent for your commercial batches contrary to the diluent recommended by the innovator / reference product.
- Scientific justification for not performing complete pharmaceutical equivalence studies as per the USP specifications against the innovator product.
- Scientific justification for not performing compatability studies of your product with the recommended diluent.
- Scientific justification for not performing test of "constituted solution" and "particulate matter in injection" in your commercial batches since these tests have been recommended in USP monograph.
- Scientific justification for your test of pH which specifies that "reconstitute the sample in 10ml WFI", however USP specifies that reconstitute as directed in the labelling and the labelling of the innovator / reference product does not recommend reconstitution in WFI.
- Scientific justification for having the method of sample solution preparation for the commercial batches which is entirely different from that specified in USP monograph.
- Scientific justification for using an entirely different formula for calculation of assay resultsof commercial batches from that specified in USP monograph.
- Scientific justification for using standard preparation containing both drug substances i.e. imipenem and cilastatin in a single injection for testing your commercial batches while USP recommends separate injections of imipenem and cilastatin standard preparation.
- Documents confirming import of drug substance having drug substance batch number 3951903005.
- Submission of fee for pre-registration changes in the drug product specifcations.

Keeping in view the above, the Board decided that the submitted stability study data is not acceptable and directed the manufacturer to either perform complete product development and stability studies or submit the aforementioned data as per USP specifications and submit data accordingly. The Board further directed the manufacturer to comply USP Specifications for already registered drug products.

Response by the firm:

Shortcoming	**Reply**
Scientific justification for not performing verification studies for analytical method of drug substance.	Method verification for the drug product (Imipenem and Cilastatin for Injection) is performed and same testing method is being used for the drug substance (because it is ready to fill powder). As method is same therefore this method verification is applicable for both. Method verification of Imipenem and Cilastatin for Injection is also provided. The verification studies

	were performed on the analytical method in which standard preparation and sample preparation is not exactly as per USP monograph.
Certificate of analysis of reference standard which is actually used in the analysis of drug substance and drug product.	In house working standard analytical report as Standardization report of API with reference standard is provided by the firm. Firm has used the premixed drug substance as working standard which is not recommended by USP.
Scientific justification for using pre-mixed drug substance having both Imipenem as well as Cilastatin as working standard for analysis of commercial batches of drug product.	We used premix of drug substance (Imipenem & Cilastatin for Injection) as working standard (batch no. 2009R0099) after standardizing it against Imipenem USP reference standard (lot no. R038R0) & Cilastatin USP reference standard (lot no. R012Y0). Firm has used the premixed drug substance as working standard which is not recommended by USP.
Scientific justification for having a master formulation containing 1106mg of drug substance in pre-mixed form containing Imipenem monohydrate, Cilastatin sodium as well as sodium bicarbonate which is equivalent to 500 mg Imipenem and 500mg Cilastatin.	Below is the calculation of fill weight if Imipenem & Cilastatin for Injection: For assay of API, attached certificate of analysis specifies NLT 400µg/mg of Imipenem and 400µg/mg of Cilastatin, while ratio of Imipenem to Cilastatin is 0.95 ~ 1.05 : 1. Therefore, in order to adjust claim of drug substance we have to choose component with lower potency. In this case Imipenem has low potency i.e. 452 µg/mg. Now, $\frac{452\mu g/mg}{1000} \times 100 = 45.2\%$ After considering both Imipenem & Cilastatin at 45.2 For Onem 500mg = $\frac{100 \times 500}{45.2\%} = 1106.19$mg/vial
Scientific justification for using water for injection as a diluent for your commercial batches contrary to the diluent recommended by the innovator / reference product.	Water for Injection will not be part of Cilsnim Injection; we have revised our artwork in order to eliminate the water for injection. The revised artwork specifies that after reconstitution administer the solution within 12 hours while the innovator product recommends that the product should be administered within 4 hours after reconstitution.
Scientific justification for not performing complete pharmaceutical equivalence studies as per the USP specification against the innovator product.	All tests that are mentioned in USP could not perform during pharmaceutical equivalence due to limited quantity of innovator sample. Therefore, we have included only all major test while performing pharmaceutical equivalence.
Scientific justification for not performing compatibility studies of your product with the recommended diluent.	Compatibility studies were performed but were not made of CTD application. Copy of compatibility studies is provided by the firm.
Scientific justification for not performing test of "constituted solution" and "particulate matter in injection" in your commercial batches since these test have been recommended in USP monograph.	As for as test of particulate matter is concerned, we have purchase Liquid particle counter in March 2020, that why this test was not performed during manufacturing of stability batches. Currently we use Liquid particle counter to perform this test. Firm has submitted following documents • Service report of IQ, OQ and PQ of Liquid Particle counter is enclosed for your review. • Report including test of particulate matter is attached. • Revised test method is also attached.
Scientific justification for your test for pH which specifies that "reconstitutes the sample in 10ml WFI", however USP specifies that reconstitute as directed in the labeling and the labeling of the innovator /	As per USP monograph pH of Imipenem and Cilastatin for Injection should be "between 6.5 and 8.5, when constituted as directed in the labeling".

reference product does not recommend reconstitution in WFI.	Based upon above statement, we reconstitute content of vial using sterile water for injection, then make the volume up to 100ml using normal saline (saline TS) and then check pH of solution using calibrated pH meter.
Scientific justification for having the method of sample solution preparation for the commercial batches which is entirely different from that specified in USP monograph.	Sample solution preparation mentioned in our testing method is same as in USP. Copy of revised test method and USP monograph is also provided. The testing method which was submitted along with the original application was not as per USP monograph.
Scientific justification for using an entirely different formula for calculation of assay results of commercial batches from that specified in USP monograph.	Formula of content of drug product is elaborated with context to standard and sample preparation procedure which has now been updated as per USP format. Documents provided are; • Copy of revised test method and USP monograph is attached.
Scientific justification for using standard preparation containing both drug substance i.e. Imipenem and Cilastatin in a single injection for testing your commercial batches while USP recommends separate injection of Imipenem and Cilastatin standard preparation	We used premix of drug substance (Imipenem & Cilastatin for Injection) as working standard while testing of our standard solution as working standard was made after standardizing it against separate Imipenem USP reference standard & Cilastatin USP reference standard. Moreover, for future we have planned to import/purchase separate Imipenem and Cilastatin and standardize against USP reference standards. Firm has used the premixed drug substance as working standard which is not recommended by USP.
Documents confirming import of drug substance having drug substance batches number 3951903005.	Firm has submitted copy of commercial invoice but for batch number 3951805003.
Submission of fee for pre-registration changes in the drug product specifcations.	Firm has submitted fee 7500/- dated 05-11-2021 for change in specifications
Keeping in view the above, the Board decided that the submitted stability study data is not acceptable and directed the manufacturer to either perform complete product development and stability studies or submit the aforementioned data as per USP specifications and submit data accordingly. The Board further directed the manufacturer to comply USP Specifications for already registered drug products.	Firm has not submitted product development and stability study data of new batches in which the development and testing is carried out as per USP specifications from initial time point.

Decision of 313th meeting of Registration Board:

Registration Board deliberated that the commercial batches manufactured by the manufacturer i.e. Global Pharmaceuticals was not developed and tested as per the USP monograph. Keeping in view the USP monograph, public assessment report of the innovator product and the data submitted by the firm, the Board decided to defer the case and advised the manufacturer to perform product development studies keeping in view the innovator product and product testing and stability studies by complying USP monograph and submit data upon completion of 6 months stability studies.

Response by the firm:

Firm has submitted completely new CTD for the same product manufactured by M/s Global Pharmaceuticals. The response of the firm along with product development and stability data was received in R&I DRAP vide Dy number 28764 dated 11-10-2022. The evaluation of newly submitted data is as under:

Dy. No. and date of submission	28764 dated 11-10-2022
Details of fee submitted	Fee for revised stability batches not submitted
The proposed proprietary name / brand name	CILSNIM 500mg Injection
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains:

	Imipenem monohydrate eq. to imipenem…….500mg Cilastatin Sodium eq. to Cilastatin ……500mg
Name and address of API manufacturer.	M/s ACS DOBFAR S.p.A Viale Addetta 2a/12-3/5 20067 Tribiano, Milano- Italy
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
Stability studies	Stability study conditions: Real time: Temp.: 30°C ± 2°C, RH: 65% ± 5% for 36 month Accelerated: Temp.: 40°C ± 2°C, RH: 75% ± 5%for 6 months Batches: (990068 8004 2, 990068 8005 2, 990068 8006 2)
Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence of their developed formulation Cinam 500mg injection (B #22A338) with reference product Cilapen 500mg Injection Batch No: CP200034 by Bosch Pharmaceuticals. The results showed that both test and reference products were comparable.
Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s ACS DOBFAR S.p.A Viale Addetta 2a/12-3/5 20067 Tribiano, Milano- Italy.
API Lot No.	990068-0008-E1
Description of Pack (Container closure system)	White to pale yellow color powder filled in clear glass vial, packed in Unit carton (1's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

		Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)	
Batch No.		22A337	22A338
Batch Size		5550 vials	5550 vials
Manufacturing Date		01-2022	01-2022
Date of Initiation		22-01-2022	22-01-2022
No. of Batches		02	
Administrative Portion			
7.	Reference of previous approval of applications with stability study data of the firm (if any)	NA	
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Italian pharmaceutical Agency valid till 26/03/2025 is submitted.	
9.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of and attested ADC (I&E) DRAP, Islamabad dated 02-06-2021 for Imipenem and cilastatin sodium sterile Batch No. 990068 0008 E1.	
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.	
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.	

Remarks OF Evaluator:

- The diluent for reconstitution used by the firm is 10ml WFI while innovator and reference product recommend 10ml 0.9% NaCl injection.
- Firm is using 1081mg/ vial which is not justified keeping in view both drug substances are available as salt form where 530mg imipenem monohydrate is equivalent to 500 mg imipenem and 530 mg cilastatin sodium salt is equivalent to 500mg cilastatin. Furthermore, the COA of API depicts that the maximum percentage of both API could be 96.6% (48.3 % of individual API).

Discussion: Registration Board was apprised that the firm has submitted response against the above mentioned observations on the day of meeting in which firm has submitted that in BMR they have mentioned 10ml WFI as diluent, however from now onwards they will use 10ml 0.9% NaCl solution as diluent as per the recommendations of innovator's product. Furthermore, the firm has also submitted calculation for fill weight of drug substance in the vials in which they have taken sodium contents as per innovator's product claim instead of using sodium contents as per the drug substance.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit full fee 75,000/- for revision of stability study data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Firm shall submit compatibility study with the 0.9%NaCl solution as diluent along with BMR of recently manufactured batches as evidence of use of the recommended diluent before issuance of Registration letter and shall use 10ml 0.9% NaCl injection as diluent for the future manufacturing of all registered drug products of applied formulation as well.**
- **Firm shall use correct fill weight per vial considering the sodium content as per the drug substance manufacturer's claim for the commercial batches and submit BMR of recently manufactured batches as evidence of correct fill weight before issuance of Registration letter.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals.**

735.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Next Pharmaceuticals Products (Pvt) Ltd. Plot # 44 A&B, Sunder Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	CCL Pharmaceuticals: GMP certificate issued on the basis of inspection conducted on 30-04-2019. Next Pharmaceuticals: GMP certificate issued on the basis of inspection conducted on 28-05-2019.
	Evidence of approval of manufacturing facility	Firm (M/s Next Pharmaceuticals) has submitted copy of Issuance of DML letter dated 31-10-2016 specifying Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 3326 dated 28-01-2021
	Details of fee submitted	Rs.50,000/- Dated 29-12-2020
	The proposed proprietary name / brand name	Nomit Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each oro-dispersible tablet contains: Domperidone……10mg
	Pharmaceutical form of applied drug	Light green colored round biconvex shaped tablet packed in Alu-PVC blister with leaflet and unit carton
	Pharmacotherapeutic Group of (API)	Anti-dopaminergic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's, 100's
	Proposed unit price	As per innovator
	The status in reference regulatory authorities	DOMPERIDONE ARROW 10 mg orodispersible tablet (ANSM France Approved)
	For generic drugs (me-too status)	Domflash ORO Tablet 10mg of Next Pharmaceuticals
	Name and address of API manufacturer.	Vasudha Pharma Chem Limited, Unit-II, Plot No. 79, Jiawaharlal Nehru Pharma city Thanam village Parawada, Mandal, Visakhapatanam Andhra Pradesh India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and

		its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Motilium tablet by Aspin Pharma
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Vasudha Pharma Chem Limited, Unit-II, Plot No. 79, Jiawaharlal Nehru Pharma city Thanam village Parawada, Mandal, Visakhapatanam Andhra Pradesh India.		
API Lot No.	BDOM/1705124		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	BU-0001	BU-0002	BU-0003
Batch Size	500,000 tablet	500,000 tablet	500,000 tablet
Manufacturing Date	02-2018	02-2018	03-2018
Date of Initiation	06-03-2018	07-03-2018	19-03-2018

No. of Batches		03
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	No inspection of Next Pharmaceuticals have been conducted on the basis of stability study data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of License retention certificate (No. 1238/AP/DCA/2017) issued by Drugs Control Administration Government of Andhra Pradesh, dated 09-02-2018. The retention certificate specifies that the validity of license has been permitted till 30-12-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 27-07-2017 specifying purchase of 30Kg Domperidone base.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed initial testing using HPLC while the 3rd and 6th month stability testing using UV method.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted manual record of logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
Justify the submission of application for contract manufacturing of tablet from a contract manufacturer since the same section i.e. Tablet (general) section is already available with CCL Pharmaceuticals.	Since, we are undergoing development / stability studies for many products and the CTD data pf the subject product was available with contract acceptor as the product is already registered for Next pharma with brand name "Domflash", registration number 084816. We hereby solicit that our concern and option may please be considered and registration of drug may please be approved. The contract manufacturing policy published vide SRO 152(I)/2014 dated 4th March 2014 does not allow contract manufacturing in such case.
Provide details regarding number of already registered products of M/s CCL Pharmaceuticals on contract manufacturing basis along with total number of approved sections.	Firm has submitted that currently they have registration of 20 products on contract manufacturing. Other than these 20 active products, firm has requested for cancellation of 17 other products that are also registered in the name of M/s CCL Pharmaceuticals on contract manufacturing basis. Firm has currently 6 active sections.
Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "*Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"* Further specify how the testing of drug substance was carried out without performing verification studies.	Firm has submitted that domflash-oro tablet is marketed since 2018 having registration number 084816. Firm has now submitted protocols for the verification studies of the drug substance dated 07-04-2021. Firm has not yet performed verification studies of the analytical procedure of drug substance. Further all the analysis of drug substance was carried out without verification of the analytical method.
Justify how the stability studies of drug substance submitted in section 3.2.S.7.3 shows different results for same batch at initial time point of accelerated and real time stability studies.	Firm has again submitted stability study data in which the results at initial time point is same for real-time and accelerated stability data.

Justify why the formulation submitted in section 3.2.P.1 has different qualitative composition as compared to the innovator / reference product.	Firm has submitted that Domflash -oro tablet is an established formulation which is being marketed since 2018having registration number 084816. There is no critical and significant side-effect observed till date. COAs of three ongoing commercial batches is attached. Firm has not submitted any justification of having a different master formulation as compared to the innovator / reference product.
Provide detailed method along with analytical details how the drug-excipient compatibility studies were performed.	Firm has submitted that Domflash -oro tablet is an established formulation which is being marketed since 2018having registration number 084816. There is no critical and significant side-effect observed till date. COAs of three ongoing commercial batches is attached. Firm has different master formulation as compared to the innovator / reference product and the firm has also not performed any compatibility studies.
Specify details including batch number and manufacturing date of the reference / comparator product against which pharmaceutical equivalence is performed.	Test product: Batch No. BU-0014 Mfg date: 09-2018 Innovator product Name: Motilium manufactured by Janssen Cilag Italy Batch No. 18JQ230 Mfg date: 10-2018 Pharmaceutical equivalence has been performed on batch manufactured on 09-2018 while stability study was initiated on batches manufactured earlier on 02-2018
Justify the results of disintegration time above 1 minute since USFDA Guidance for Industry on Orally Disintegrating Tablets specifies that "*Based on the original product rationale and Agency experience, we recommend that, in addition to the original definition, ODTs be considered solid oral preparations that disintegrate rapidly in the oral cavity, with an in-vitro disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method or alternative*."	Firm has submitted that based on WHO guidelines, Revision of monograph on tablets for additional in international pharmacopoeia dated March 2011 mentions disintegration time within 3 minutes. As our product is non pharmacopoeial so we are using this WHO guidelines. The quoted reference by the firm is for dispersible tablet while the applied formulation is orally disintegrating / oro-dispersible tablet.
Justify why dissolution test was not performed during pharmaceutical equivalence study.	Firm has submitted that dissolution test is not applicable for oro-dispersible tablets "USP general chapter <1711> oral solid dosage forms - dissolution testing" recommends dissolution testing.
Justify why comparative dissolution profile is not performed.	Firm has submitted that dissolution test is not applicable for oro-dispersible tablets "USP general chapter <1711> oral solid dosage forms - dissolution testing" recommends dissolution testing.
Justify the drug product specifications without the test of dissolution, since dissolution test is recommended for oro-dispersible tablets in USP general chapter <1711> oral solid dosage forms - dissolution testing.	Firm has submitted that USP general chapter <1711> oral solid dosage forms – dissolution testing does not include dissolution test. However the said general chapter recommends dissolution testing for oro dispersible tablet.
The analytical procedures of drug product (section 3.2.P.5.2) specifies both UV as well as HPLC method for identification as well as assay testing of the drug product. Clarification is required regarding which method will be used for testing of the product for batch release and stability studies.	Domflash 10mg tablet orodispersible tablet was developed in house for testing on UV and HPLC. For batch release and stability studies both methods are validated.
The stability batches were manufactured in February / Mach 2018 while the analytical method for drug product was validated on 09-2019 and 12-2019. Justify how the testing of these batches were carried out without validating the analytical method.	The product has been developed and marketed earlier as per previous practice. Now we have performed validation studies as per requirement and the results obtained from non-validated method were found same as that of validated method with no deviations.
Justify why disintegration test was not performed during stability studies.	Initially disintegration test was not performed, but now as per updated requirements disintegration test is

	incorporated in the testing and implemented on all batches till date.
The initial stability study testing was performed using HPLC method while the 3rd and 6th month stability testing was performed using UV method. Justify why the analytical method was changed during the stability studies.	Domflash 10mg tablet orodispersible tablet was developed in house for testing on UV and HPLC. For batch release and stability studies both methods are validated.
The submitted record of data logger of stability chambers show only 2 temperature and humidity record readings per day (i.e. 09:00-11:00 and 15:00-17:00). Justify how only two readings per day can demonstrate the temperature and humidity control throughout the day.	Initially manual monitoring of temperature and humidity was done. Due to manual monitoring, recording the temperature and humidity was taken twice a day. Our system is now upgraded and we have successfully installed digital data logger. With data logger monitoring of temperature and humidity was taken after every 5 minutes. The submitted record of data logger is of year 2020 while the stability batches were kept in chamber in March 2018.
The submitted record of data logger of stability chambers show record of working days only, while there is no record available for weekends (i.e. Saturday and Sunday) and other public holidays (i.e. Eid holidays). Justify why there was no mechanism for recording temperature and humidity readings during the off days and how stability studies can be concluded without having the capacity to identify any deviation in temperature and humidity in the stability chambers.	

Decision of 307th meeting of Registration Board:

Registration Board after thorough deliberation and keeping in view the review of innovator product, guidelines of USFDA for orally disintegrating tablets and the recommendations of USP general chapter <1711> oral solid dosage forms - dissolution testing decided that since the contract manufacturer i.e. M/s Next Pharmaceuticals is also manufacturing the same product for its own use therefore the technical queries and onservations on the contract manufactured product shall also apply on the self manufactured product of the firm. Based on the discussion, Board decided as under:

- Submission of product development and stability study data of the recently manufactured batches by M/s Next Pharmaceuticals Products (Pvt) Ltd since their formulation is qualititaively different from that of the innovator product and the firm has not performed drug-excipient compatability studies, the acceptance criteria of disintegration test is is more than 1 minute while for oro-dispersible tablets USFDA recommends disintegration time of less than 30 seconds and the finished product specifications or product development studies does not include dissolution test which is recommended in USP general chapter <1711>.
- Scientific justification of having a master formulation which is qualitatively different from that of innovator product without performance of drug-excipient compatibility studies
- Scientific rational for the adaptation of acceptance criteria of disintegration test i.e. more than 1 minute while for oro-dispersible tablets USFDA recommends disintegration time of less than 30 seconds.
- Scientific rational for not performing dissolution test during product development studies, batch release as well as during stability studies while the USP general chapter <1711> oral solid dosage forms - dissolution testing recommends dissolution testing for orodispersibe tablets.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Registration Board after thorough deliberation and keeping in view the review of innovator product, guidelines of USFDA for orally disintegrating tablets and the recommendations of USP general chapter <1711> oral solid dosage forms - dissolution testing decided that since the contract manufacturer i.e. M/s Next Pharmaceuticals is also manufacturing the same product for its own use therefore the technical queries and onservations on the contract manufactured product shall also apply on the self manufactured product of the firm	No response from the manufacturer M/s Next Pharmaceuticals have been received in this regard.
2.	Submission of product development and stability study data of the recently manufactured batches by M/s Next Pharmaceuticals Products (Pvt) Ltd since their formulation is qualititaively different	Firm has not submitted any product development data or revised formulation / composition, drug-excipient compatability studies, pharmaceutical equivalence and CDP studies.

	from that of the innovator product and the firm has not performed drug-excipient compatability studies, the acceptance criteria of disintegration test is is more than 1 minute while for oro-dispersible tablets USFDA recommends disintegration time of less than 30 seconds and the finished product specifications or product development studies does not include dissolution test which is recommended in USP general chapter <1711>.	A Brief pharmaceutical development report has been submitted by CCL pharmaceuticals while the product manufacturer is Next Pharmaceuticals. Moreover firm has submitted stability study data of three batches in which the first batch was manufactured **in May 2021 while the 307th meeting of Registration Board in which this case was considered, was conducted on 8,9 and 10th June 20221.**
3.	Scientific justification of having a master formulation which is qualitatively different from that of innovator product without performance of drug-excipient compatibility studies	No response submitted by the firm
4.	Scientific rational for the adaptation of acceptance criteria of disintegration test i.e. more than 1 minute while for oro-dispersible tablets USFDA recommends disintegration time of less than 30 seconds.	No response submitted by the firm
5.	Scientific rational for not performing dissolution test during product development studies, batch release as well as during stability studies while the USP general chapter <1711> oral solid dosage forms - dissolution testing recommends dissolution testing for orodispersibe tablets.	No response submitted by the firm

Firm has submitted another response dated 21-11-2022 in which the firm has submitted stability study data of 3 newly manufactured batches for the drug product manufactured from same source of API. Firm has also perfomed dissolution test on the newly submitted data. The details of the stability data is as under:

STABILITY STUDY DATA

Manufacturer of API	Vasudha Pharma Chem Limited, Unit-II, Plot No. 79, Jiawaharlal Nehru Pharma city Thanam village Parawada, Mandal, Visakhapatanam Andhra Pradesh India.		
API Lot No.	BDOM/1902010		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	BU-0053	BU-0054	BU-0055
Batch Size	38815 Packs	39488 Packs	39066 Packs
Manufacturing Date	05-2021	08-2021	11-2021
Date of Initiation	11-06-2021	27-08-2021	07-12-2021
API Lot No.	BDOM/1902010	BDOM/2105066	BDOM/2105066
No. of Batches	03		

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit fee 75,000/- for revision of stability study data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

736.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Farm Aid Pharmaceuticals, 3/2 Phase I & II Hattar, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 19-10-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cure Laboratories dated 18-02-2021 based on the inspection dated 12-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License of M/s Cure Laboratories (Pvt) Ltd dated 05-03-2019 specifying Dry Powder suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10738: 07-04-2021
	Details of fee submitted	PKR 50,000/-: 23-11-2020
	The proposed proprietary name / brand name	**FOFAM 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……100mg
	Pharmaceutical form of applied drug	Off white powder filled in amber colored glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml, 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefspan dry suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00243/178/2019		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19001	19002	19006
Batch Size	5000 bottles	5000 bottles	5000 bottles
Manufacturing Date	11-2019	11-2019	12-2019
Date of Initiation	06-12-2019	02-12-2019	17-12-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous product specific inspectinon of the firm has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-

		2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 13-11-2019 specifying purchase of 25Kg Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Justify the analytical procedure and validation studies of drug substance in which the injection volume is 20µl and the retention time is around 5 minutes and the total run time is 7 minutes, while as per USP monograph, the injection volume is 10 µl and the retention time is 10 min. Justify how you have deviated from the USP monograph and performed verification studies.	Previously the QC department not following USP monograph for analytical method verification studies. That's why there were deviations from USP monograph like injection volume were taken as 20uL and run time as 7 minutes. Therefore we have re-performed the analytical method validation studies in line with USP monograph and the analytical method verification report is attached herewith. **Firm has not justified their previous practice. Moreover the newly submitted verification studies are not as per ICH and USP recommendations and also does not specify any date on which these studies were conducted.**
As per the analytical procedure of drug substance, the concentration of standard solution is 0.2mg/ml while you have defined 10ppm solution as 100% solution in accuracy studies. Justify how your verification studies are representative of the same analytical procedure.	Previously the QC department not following USP monograph for analytical method verification studies. That's why there were deviations from USP monograph like single reading of a solution among two analysts. **The newly submitted verification studies are not as per ICH and USP recommendations and also does not specify any date on which these studies were conducted. Moreover the specificity studies does not specify the solution concentration.**
You have specified that 30ml bottle containing cefixime powder for suspension is to be reconstituted with 20ml water for injection. Justify how this reconstitution will yield similar concentration of the drug as hat of the innovator product.	Firm has submitted that we have followed cefspan 100mg/5ml powder for oral suspension as our innovator brand for product development. **The innovator product is available as 50ml, 75ml and 100ml bottle only.**
Justify why the test for uniformity of dosage unit is not added in drug product specification as recommended in USP monograph. Revise your product specifications in line with USP monograph along wih submission of fee for revision of specifications.	Firm has revised the specifications along with submission of fee PKR 7500/-vide slip number 6290135711 dated 24-01-2022. **Moreover, the new method again does not provide detailed method of sample solution preparation.**
Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.	Firm has revised the specifications without **submission of any fee**. **Moreover, the new method again does not provide detailed method of sample solution preparation.**
Justify the alternate method for assay testing of the drug product which is based on UV analysis.	We haven't used any alternate method or analysis of finished product. The UV method for assay was submitted mistakenly.
You have submitted the results of verification studies of drug substance in section 3.2.P.5.3 under the heading of verification studies of the drug product. Justify how same	Previously the QC department not following USP monograph for analytical method verification studies. That's why there were deviations from USP monograph.

results for all the parameters can be achieved for drug substance and drug product.	Therefore, we have re-performed the analytical method validation studies. **The submitted studies again show similar results from that of drug substance verification studies. Moreover, the HPLc chromatograms show 1uL injection volume and various chromatograms have been printed before the execution time of the relevant chromatogram.**
Justify the significant difference in assay for batch No. 19002 in accelerated stability studies where the assay declined from 110% at initial time point to 99.03% after 6 months. This difference is considered to be significant change as per the ICH guidelines, justify how your stability studies for this batch may be considered acceptable in the light of ICH guidelines keeping in view that the real time stability studies are also available for 9 months and the same trend is also observed in real time stability studies.	The accelerated stability studies of the Batch No. 19002 in which the assay declined from 110% at initial month and 99.03% at 6th month, this **may** be due to mishandling by the analyst or **may** be due to dilution factor. If our product is unstable then same trend should be in other batches of this product. Other two batches are not showing this trend it clearly depicts the **mishandling or wrong dilution by the analyst.** The response of the firm regarding **mishandling or wrong dilution by the analyst raise question on the complete data and testing since the firm is also not complying USP specifications and also not performed the verification studies.**
Justify why the assay test is performed using UV method while the method of analysis of drug substance manufacturer, innovator product and USP monograph is based on HPLC method. Furthermore, the verification studies were also conducted for HPLC method. Justify how you have released the commercial batches without testing the product as per USP specifications and also performed stability studies.	We have checked the batches of Fixikef 100mg/5ml dry suspension on HPLC as well on that time before release of the batches. We have performed on UV for verification of the results only. Due to some mis-understanding the UV report was submitted. **The firm in its response in a question above stated that "*We haven't used any alternate method or analysis of finished product. The UV method for assay was submitted mistakenly*". The response of the firm is contradictory among different points.**
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (Invoice # 1013, customer PO# NIL, Proforma invoice No. PL/P-INV/HO/663, DN No. 1013) dated 13-11-2019 specifying purchase of 25Kg Cefixime (micronized). **However, the invoice submitted by the firm does not seems to be real and may require to be verified.**
Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted that they have submitted 21 CFR compliance report in Fofam 100mg/5ml suspension file. **However, audit trail report was not submitted.**
You have specified that the capacity of double cone mixer for dry suspension is 200Kg, while the batch size for which stability data is submitted is 85Kg. Justify how uniform mixing was carried out using a mixer of two times higher capacity than the batch size.	We have initially sieved all the ingredients through sieve # 30 and then loaded into mixer then run for 45 minutes at 30 RPM. Then we intimated for sampling for QC analysis. QC has tested the sample and released the batch for filling. Our mixing method is validated for this batch size and all the batches are showing the results within the specified limits. Therefore uniform mixing of 85Kg can be done in a 200Kg capacity.

Decision of 316th meeting of Registration Board:

Deferred for following:

- Scientific justification for testing commercial batches of the drug product using specifications different from that specified in USP monograph.
- Scientific justification for having drug product specifications and testing method different from that specified in USP monograph.
- Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.
- Scientific justification for stability testing of the product using UV method which is not recommended by USP monograph.
- Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Submission by the firm:

Sr. No	Reason for deferment	Respose by the firm
1.	Scientific justification for testing commercial batches of the drug product using specifications different from that specified in USP monograph.	We have performed all the tests of the finished products of the commercial batches Fixikef 100mg/5ml Suspension as per USP Monograph but during typing of Reports our analyst forget to mention all the tests / parameters on the Finished Product Reports. Now we have corrected the COAs of the Finished Products of these Commercial Batches of Fixikef 100mg/5ml Suspension and a copy of the reports are submitted.
2.	Scientific justification for having drug product specifications and testing method different from that specified in USP monograph.	Initially there were some mistakes in the Specifications and Testing Method of the finished product. Now we have corrected the Specifications and SAP as per Current USP Monograph and a copy of Specification and SAP of Fixikef 100mg/5ml Suspension is submitted. **The revised specifications specify that revision number is 00 and the amendment history also does not show any changes in specifications.**
3.	Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.	We have performed all the parameters of method verification studies of finished product but there may be some variation from ICH Guideline due handling from the analyst or may be dilution factor. Therefore, we will be careful next time and try to perform as per ICH Guidelines.
4.	Scientific justification for stability testing of the product using UV method which is not recommended by USP monograph.	Initially there were some mistakes our Quality Control end that they haven't follow USP monograph in real sense and perform stabilities on UV Spectrophotometer. When we realized this mistake we have performed remaining stability time points on HPLC Spectrophotometer. We enclosed a copy of stability of remaining time points performed on HPLC Spectrophotometer. Firm has now submitted HPLC chromatograms for assay testing dated 28-10-2021 in which only 1 standard injection was used and the calculation formula was also not as per USP. Moreover firm has submitted HPLC data of 28-10-2021 while 316th meeting in which this case was dicusedd was conducted in March 2022.
5.	Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.	Firm has submitted audit trail report of 2022 and digital data logger record of stability chambers.

Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.**
- **Firm shall submit record of testing of recently manufactured commercial batches as per USP monograph before issuance of Registration letter.**

737.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Farm Aid Pharmaceuticals, 3/2 Phase I & II Hattar, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 19-10-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cure Laboratories dated 18-02-2021 based on the inspection dated 12-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License of M/s Cure Laboratories (Pvt) Ltd dated 05-03-2019 specifying Dry Powder suspension (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8860: 18-03-2021
	Details of fee submitted	PKR 50,000/-: 23-11-2020
	The proposed proprietary name / brand name	**FOFAM 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	Off white powder filled in amber colored glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml, 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefspan 200mg/5ml dry suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00243/178/2019		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19003	19007	20002
Batch Size	3000 bottles	3000 bottles	3000 bottles
Manufacturing Date	12-2019	12-2019	01-2020
Date of Initiation	04-12-2019	26-12-2019	08-01-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous product specific inspectinon of the firm has been conducted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 13-11-2019 specifying purchase of 25Kg Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Justify the analytical procedure and validation studies of drug substance in which the injection volume is 20µl and the retention time is around 5 minutes and the total run time is 7 minutes, while as per USP monograph, the injection volume is 10 µl and the retention time is 10 min. Justify how you have deviated from the USP monograph and performed verification studies.	Previously the QC department not following USP monograph for analytical method verification studies. That's why there were deviations from USP monograph like injection volume were taken as 20uL and run time as 7 minutes. Therefore we have re-performed the analytical method validation studies in line with USP monograph and the analytical method verification report is attached herewith. **Firm has not justified their previous practice. Moreover the newly submitted verification studies are not as per ICH and USP recommendations and also does not specify any date on which these studies were conducted.**
As per the analytical procedure of drug substance, the concentration of standard solution is 0.2mg/ml while you have defined 10ppm solution as 100% solution in accuracy studies. Justify how your verification studies are representative of the same analytical procedure.	Previously the QC department not following USP monograph for analytical method verification studies. That's why there were deviations from USP monograph like single reading of a solution among two analysts. **The newly submitted verification studies are not as per ICH and USP recommendations and also does not specify any date on which these studies were conducted. Moreover, the specificity studies does not specify the solution concentration.**
Justify the total fill weight of 14.940gm per bottle, since you have mentioned exactly same quantities of each excipient and have used double quantity of the drug substance as that provided in 100mg/5ml suspension.	We have used quantities of all the excipients are same except that of sugar, which adjusted in Fixikef 200mg/5ml DS for double quantity of API.
You have specified that 60ml bottle containing cefixime powder for suspension is to be reconstituted with 20ml water for injection. Justify how this reconstitution will yield similar concentration of the drug as hat of the innovator product.	Firm has submitted that the 60ml bottle contains 17.20g powder and it will be reconstituted using 20ml sterile water for injection.
Justify why the test for uniformity of dosage unit is not added in drug product specification as recommended in USP monograph. Revise your product specifications in line with USP monograph along wih submission of fee for revision of specifications.	Firm has revised the specifications along with submission of fee PKR 7500/-vide slip number 6290135711 dated 24-01-2022. **Moreover, the new method again does not provide detailed method of sample solution preparation.**
Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.	Firm has revised the specifications without **submission of any fee**. **Moreover, the new method again does not provide detailed method of sample solution preparation.**

Justify the alternate method for assay testing of the drug product which is based on UV analysis.	We haven't used any alternate method or analysis of finished product. The UV method for assay was submitted mistakenly.
You have submitted the results of verification studies of drug substance in section 3.2.P.5.3 under the heading of verification studies of the drug product. Justify how same results for all the parameters can be achieved for drug substance and drug product.	Previously the QC department not following USP monograph for analytical method verification studies. That's why there were deviations from USP monograph. Therefore, we have re-performed the analytical method validation studies. **The submitted studies again show similar results from that of drug substance verification studies. Moreover, the HPLc chromatograms show 1uL injection volume and various chromatograms have been printed before the execution time of the relevant chromatogram.**
Justify the significant difference in assay for batch No. 20002 in accelerated stability studies where the assay declined from 103% at initial time point to 97.47% after 6 months. This difference is considered to be significant change as per the ICH guidelines, justify how your stability studies for this batch may be considered acceptable in the light of ICH guidelines.	The accelerated stability studies of the Batch No. 2002 in which the assay declined from 103% at initial month and 97.47% at 6th month, this **may** be due to mishandling by the analyst or **may** be due to dilution factor. If our product is unstable then same trend should be in other batches of this product. Other two batches are not showing this trend it clearly depicts the **mishandling or wrong dilution by the analyst.** The response of the firm regarding **mishandling or wrong dilution by the analyst raise question on the complete data and testing since the firm is also not complying USP specifications and also not performed the verification studies.**
Justify why the assay test is performed using UV method while the method of analysis of drug substance manufacturer, innovator product and USP monograph is based on HPLC method. Furthermore, the verification studies were also conducted for HPLC method. Justify how you have released the commercial batches without testing the product as per USP specifications and also performed stability studies.	We have checked the batches of Fixikef 100mg/5ml dry suspension on HPLC as well on that time before release of the batches. We have performed on UV for verification of the results only. Due to some mis-understanding the UV report was submitted. **The firm in its response in a question above stated that "*We haven't used any alternate method or analysis of finished product. The UV method for assay was submitted mistakenly*". The response of the firm is contradictory among different points.**
Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (Invoice # 1013, customer PO# NIL, Proforma invoice No. PL/P-INV/HO/663, DN No. 1013) dated 13-11-2019 specifying purchase of 25Kg Cefixime (micronized). **However, the invoice submitted by the firm does not seems to be real and may require to be verified.**
Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted that they have submitted 21 CFR compliance report in Fofam 100mg/5ml suspension file. **However, audit trail report was not submitted.**
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted that they have submitted temperature and humidity logger report in Fofam 100mg/5ml suspension file. **However, data logger report was not submitted.**
You have specified that the capacity of double cone mixer for dry suspension is 200Kg, while the batch size for which stability data is submitted is 85Kg. Justify how uniform mixing was carried out using a mixer of two times higher capacity than the batch size.	We have initially sieved all the ingredients through sieve # 30 and then loaded into mixer then run for 45 minutes at 30 RPM. Then we intimated for sampling for QC analysis. QC has tested the sample and released the batch for filling. Our mixing method is validated for this batch size and all the batches are showing the results within the specified limits. Therefore uniform mixing of 51Kg can be done in a 200Kg capacity.

Decision of 316th meeting of Registration Board:

Deferred for following:

- Scientific justification for testing commercial batches of the drug product using specifications different from that specified in USP monograph.

- Scientific justification for having drug product specifications and testing method different from that specified in USP monograph.
- Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.
- Scientific justification for stability testing of the product using UV method which is not recommended by USP monograph.
- Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Submission by the firm:

Sr. No	Reason for deferment	Respose by the firm
1.	Scientific justification for testing commercial batches of the drug product using specifications different from that specified in USP monograph.	We have performed all the tests of the finished products of the commercial batches Fixikef 100mg/5ml Suspension as per USP Monograph but during typing of Reports our analyst forget to mention all the tests / parameters on the Finished Product Reports. Now we have corrected the COAs of the Finished Products of these Commercial Batches of Fixikef 100mg/5ml Suspension and a copy of the reports are submitted.
2.	Scientific justification for having drug product specifications and testing method different from that specified in USP monograph.	Initially there were some mistakes in the Specifications and Testing Method of the finished product. Now we have corrected the Specifications and SAP as per Current USP Monograph and a copy of Specification and SAP of Fixikef 100mg/5ml Suspension is submitted. **The revised specifications specify that revision number is 00 and the amendment history also does not show any changes in specifications.**
3.	Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.	We have performed all the parameters of method verification studies of finished product but there may be some variation from ICH Guideline due handling from the analyst or may be dilution factor. Therefore, we will be careful next time and try to perform as per ICH Guidelines.
4.	Scientific justification for stability testing of the product using UV method which is not recommended by USP monograph.	Initially there were some mistakes our Quality Control end that they haven't follow USP monograph in real sense and perform stabilities on UV Spectrophotometer. When we realized this mistake we have performed remaining stability time points on HPLC Spectrophotometer. We enclosed a copy of stability of remaining time points performed on HPLC Spectrophotometer. Firm has now submitted HPLC chromatograms for assay testing dated 28-10-2021 in which only 1 standard injection was used and the calculation formula was also not as per USP. Moreover firm has submitted HPLC data of 28-10-2021 while 316th meeting in which this case was dicusedd was conducted in March 2022.
5.	Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.	Firm has submitted audit trail report of 2022 and digital data logger record of stability chambers.

Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.**
- **Firm shall submit record of testing of recently manufactured commercial batches as per USP monograph before issuance of Registration letter.**

738.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Farm Aid Group Pharmaceuticals, 3/2 Phase-I & II Hattar Industrial Estate Hattar, Haripur.**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 19-10-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cure Laboratories dated 18-02-2021 based on the inspection dated 12-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License of M/s Cure Laboratories (Pvt) Ltd dated 05-03-2019 specifying Dry Powder vial (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16367: 14-06-2021
	Details of fee submitted	PKR 50,000/-: 23-11-2020 + PKR 25,000/: 20-01-2022
	The proposed proprietary name / brand name	**SOCEF 250mg Injection IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma

	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Oxidil 250mg Injection of M/s Sami Pharma.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
API Lot No.	Q012002060
Description of Pack (Container closure system)	Glass vials
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20028	20029	20030
Batch Size	3000 vials	3000 vials	3000 vials
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	17-06-2020	18-06-2020	18-06-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous product specific inspectinon of the firm has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SX20180229) issued by CFDA China dated 06-06-2018. The GMP certificate is valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 200Kg Ceftriaxone sodium (sterile) dated 04-05-2020. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail report of 2022 and 2021 **but the audit trail report for the product testing of the applied product is not provided.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has submitted fee challan for differential fee of PKR 25,000 dated 20-01-2022.
Justify the drug substance specifications submitted in section 3.2.S.4.1 which states that the material is non-sterile and the assay limit is 98 – 102% which is contrary to that specified in USP monograph for ceftriaxone for injection. Furthermore, clarify whether you have used sterile ready to fill drug substance or non-sterile ceftriaxone sodium.	There was a typographic mistake that non-sterile was mentioned and the assay limit was mentioned 98-102%. Actually, we have used sterile ceftriaxone sodium and just filled in vials under aseptic conditions. Actual assay limit for ceftriaxone sterile was NLT 795ug/mg on anhydrous basis. **The assay limit defined by FPP manufacturer is NLT 795ug/mg, while the assay limit of API manufacturer is NLT 840 ug/mg.**
Justify how the drug substance batch No. Q012002060 was released on 18-05-2020 without performing sterility test since this test is mentioned in the drug substance specifications as well as COA of drug substance manufacturer. Justify how 200kg material was released for production without performing sterility test.	At the time of import from the source SINO PHARM CHINA, No vendor sample was provided by the Supplier. Therefore, the container was opened in the sterile area under laminar flow hood and take sample for Chemical and Microbiological Tests. The chemical test was conducted at the spot and microbiological test (sterility) initiated by same day but on the basis of chemical analysis

	and the nature of sterile powder that can't be waited for sterility completion as sterility is for 14 days, we have decided to release the lot for production use **conditionally** for Filling and Sealing only. The condition was that after complying sterility we can label or pack the filled vials. On the Release Report the Analyst Forget to mention **Conditionally Released**, Now corrected the Release report and is attached. The Endotoxin and sterility reports are also attached herewith.
Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product as per USP specifications. Justify how only pH and assay test can demonstrate pharmaceutical equivalence.	Firm has again submitted pharmaceutical equivalence study report with oxidil injection in which more tests are also incorporated in the test report **without justifying the previously submitted studies.**
Justify why the pharmaceutical equivalence is performed against comparator product instead of testing against the innovator product.	We have performed Pharmaceutical Equivalence Studies with Comparator Product (Oxidil 250mg Injection IM of Sami Pharmaceuticals) because we are unable to arrange innovator pack of Rocephin 250mg Injection IM due to shortage of supply. Kindly accept the Pharmaceutical Equivalence Studies with Oxidil as an Exceptional Case Please.
Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc. Further justify why complete process validation is not performed since commercial batches of the drug product have been manufactured by the manufacturer.	Firm has submitted revised process validation protocols **without justifying the previously submitted protocols.**
Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain important tests as recommended by USP including test for constituted solution, particulate matter in injection, crystallinity and complete assay test.	Firm has submitted revised specifications of the drug product **without justifying the previously submitted justifications.**
Provide detailed testing method for the drug product as per the USP specifications since the submitted method is not complete. Also submit fee for revision of specifications in the light of USP monograph.	Firm has submitted revised specifications of the drug product without justifying the previously submitted justifications. **However the revised method of analysis is also in variation to USP in terms of the assay test since USP recommends two different type of test for the assay and the sample solution preparation method of USP is in mobile phase, while the firm is preparing sample solution in 1% lignocaine.** Firm has also submitted fee PKR 7500 for revision of specifications dated 18-01-2022.
Clarify the sample solution preparation method in your analysis which states "constitute ceftriaxone for injection in a volume of water corresponding to the volume of solvent specified in the labelling". Specify what is the exact volume in which reconstitution is to be carried out instead of mentioning generalized statements.	Break the tip of the Ampoule of Lignocaine 1% Solution for injection 2ml. Draw the Solution inside in syringe (Almost drawable volume is 1.8ml). Then inject the solution into the Niasef 250mg Injection IM Vial and reconstitute for 5 minutes until clear solution is obtained. Then leave the solution for 1-2 minutes to clear the bubbles inside, then take a fresh syringe and draw the ceftriaxone solution into the syringe and inject through IM route. **Firm has submitted method for administration of the injection instead of providing detailed method for sample solution preparation in assay method.**
Justify how three commercial batches were released for commercial use without performing complete tests as specified in USP monograph.	**Firm has not submitted any response**
The batches are released after 16-06-2020, while the stability studies were initiated on 02-06-2020. Justify how the batch could be initiated for stability studies before the batch release.	We have initiated stability 02-06-2020 because our micro Lab completed the stability of filled vials on 02-06-2020. We have packed the required stability packs on same date manually i.e. 02-06-2020 but remaining packing of whole batch was carried out by production department on 16-06-2020 and our QC Released the batch on 16-06-2020 after checking retained packs received on 16-06-2020.

Justify why the test for bacterial endotoxin, sterility, water contents, constituted solution etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life.	**Firm has not submitted any response**
Justify the raw data sheets in which sample preparation method is incomplete.	Firm has still provided incomplete raw data sheets in which the calculation procedure is different from that specified in the analytical method of the firm, moreover **firm is preparing sample solution in 1% lignocaine contrary to the recommendations of USP.**
Justify how only single value of peak area of standard and sample is used to calculate the assay of drug product during stability studies.	**Firm has not submitted any justification,** instead provided new chromatograms in which 2 standard injections are used which is still not as per the recommendations of USP.
Provide complete record of the stability testing of each batch with proper separators in a sequence instead of separately providing the data without any sequence.	**Firm has again submitted data without any proper sequence again and the raw data sheets are also incomplete since they only contain single value of standard and sample area, further the potency of standard used in raw data sheets are 830.4, while the actual potency of standard as per COA submitted by the firm is 843. Furthermore, the sample solution prepared by the firm is in lignocaine contrary to USP recommendations.**
Justify the batch manufacturing record in which the exact time of start and end of sterilization, filling of vial and sampling etc is not mentioned.	This was a typographical mistake that the BMRs should include Sterilization Start and End Time not mentioned. Actually the sterilization start and End time was noted on the Sterilization Log book. Now we have corrected the BMR and included Sterilization Start and End time.

Decision of 316th meeting of Registration Board:

Deferred for following:

- Scientific justification for assay limit as NLT 795ug/mg, while the assay limit of drug substance manufacturer is NLT 840 ug/mg.
- Scientific justification for testing commercial batches of the drug product using specifications different from that specified in USP monograph.
- Scientific justification for having drug product specifications and testing method different from that specified in USP monograph.
- Scientific justification how three commercial batches were released in the market without complete testing as per USP monograph.
- Scientific justification why the test for bacterial endotoxin, sterility, water contents, constituted solution etc is not performed during stability studies.
- Scientific justification how only single value of peak area of standard and sample is used to calculate the assay of drug product during stability studies.
- Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Submission by the firm:

Sr. No	Reason for deferment	Respose by the firm
1.	Scientific justification for assay limit as NLT 795ug/mg, while the assay limit of drug substance manufacturer is NLT 840 ug/mg.	Initially we have followed USP Monograph for testing of Ceftriaxone Sodium API and the limit for Assay of Ceftriaxone Sodium was 795ug/mg. But after discussion with concerned Assistant Director (AD) we have realized that we should follow the narrow range for Assay of Ceftriaxone Sodium. Therefore, we have changed the Assay Limit and the new limit (as per API Supplier Chinese Pharmacopeia) we have adopted 840ug/mg for Assay of Ceftriaxone Sodium. We will follow 840ug/mg

		as Assay Limit for future API (Ceftriaxone Sodium) lots testing.
2.	Scientific justification for testing commercial batches of the drug product using specifications different from that specified in USP monograph.	We have performed all the tests of the finished products of the commercial batches NIASEF 250MG INJECTION IM as per USP Monograph but during typing of Reports our analyst forget to mention all the tests / parameters on the Finished Product Reports. Now we have corrected the COAs of the Finished Products of these Commercial Batches of NIASEF 250MG INJECTION IM and a copy of the reports are attached herewith for your review please.
3.	Scientific justification for having drug product specifications and testing method different from that specified in USP monograph.	Initially there were some mistakes in the Specifications and Testing Method of the finished product. Now we have corrected the Specifications and SAP as per Current USP Monograph and a copy of Specification and SAP of Socef 250mg Injection IM is attached herewith. We have already paid a Fee of RS 7500/- for change of Specifications of Socef 250mg Injection IM.
4.	Scientific justification how three commercial batches were released in the market without complete testing as per USP monograph.	We have performed all the tests of the finished products of the commercial batches NIASEF 250MG INJECTION IM as per USP Monograph but during typing of Reports our analyst forget to mention all the tests / parameters on the Finished Product Reports. Now we have corrected the COAs of the Finished Products of these Commercial Batches of NIASEF 250MG INJECTION IM and a copy of the reports are attached herewith for your review please.
5.	Scientific justification why the test for bacterial endotoxin, sterility, water contents, constituted solution etc is not performed during stability studies.	We have performed all the tests of the stability batches at every interval of time but at the time of typing of Stability Reports our analyst forget to mention on stability sheets. Now after 9th month we have performed all the parameters as per USP Monograph and the results of stability studies on 12th month 18th month and a current time point is attached for your review and evaluation.
6.	Scientific justification how only single value of peak area of standard and sample is used to calculate the assay of drug product during stability studies.	Initially we have performed stability studies with a single value of standard and a sample but when we realize our mistake than we have corrected our studies with three standards and two samples. The stability data time points with 12th month, 18th month and current point is as per three standards and two samples. **Firm is now using 2 standard injection.**
7.	Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.	Firm has submitted audit trail report of 2022 and digital data logger record of stability chambers.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.**

- **Firm shall submit record of testing of recently manufactured commercial batches as per USP monograph before issuance of Registration letter.**

739.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt) Ltd. Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 02-08-2021 is submitted.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-03-2022 based on inspection dated 11-02-2019. As per the certificate, it was valid till 09-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML of M/s Vision Pharmaceuticals DML No 000517 dated 07-06-2021. Firm has also submitted copy of letter dated 09-12-2021 which specifies that CLB in its 283rd meeting held on 28th October 2021 also approved renewal of DML for Liquid Injectable (LVP) General Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23864: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 06-08-2021
	The proposed proprietary name / brand name	**JYTHON 600mg/300ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of 300ml Contains: Linezolid…..…600mg
	Pharmaceutical form of applied drug	Liquid infusion
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use
	Reference to Finished product specifications	In-house specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zyvox IV **(USFDA** Approved)
	For generic drugs (me-too status)	Nezkil Infusion by Continental pharma
	Name and address of API manufacturer.	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and

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

STABILITY STUDY DATA

Manufacturer of API	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.		
API Lot No.	OP-LID/10/17/107		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	1217901	1217902	1217904
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	12-2017	12-2017	12-2017
Date of Initiation	27-12-2017	29-12-2017	29-12-2017
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 68951/TS/2021) issued by Drugs control administration, Government of Telangana dated 20-09-2021. The GMP certificate is valid till 19-09-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 08-11-2017 specifying import of 50Kg Linezolid. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC system are not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify the manufacturing of 300ml glass vial (linezolid 600mg/300ml Infusion), while your approved manufacturing facility is "Liquid Injectable Vial SVP (General) section".	Firm has also submitted copy of letter dated 09-12-2021 which specifies that CLB in its 283rd meeting held on 28th October 2021 also approved renewal of DML for Liquid Injectable (LVP) General Section.
2.	The drug substance manufacturer has specified HPLC test for assay of drug substance while the drug product manufacturer has specified UV method for assay of drug substance. Justify how drug product manufacturer can adopt different test for assay method from that recommended by the drug substance manufacturer.	The drug substance testing was done by UV method at that time, but currently we are using HPLC method for both API and product.
3.	Submit COA of relevant batch of API used in the manufacturing of batches for which stability study data is submitted in section 3.2.P.8.3 from both drug substance manufacturer as well as drug product manufacturer in section 3.2.S.4.4, since you have submitted COA of batch number OP-LID/10/17/107 (Mfg date: 09-2017), while as per the submitted import documents the lot number of the API is OP-LID/07/18/077 (Mfg date: 05-2018) and the three stability batches are manufactured in 12-2017.	Firm has submitted ADC attested commercial invoice for lot number OP-LID/10/17/107.
4.	Innovator drug product is using sodium hydroxide and/or hydrochloric acid for ataining the pH within a narrow range of 4.4-5.2 while your master formulation does not specify the use of any such ingredient. Justification is required in this regard.	For pH adjustment we had mentioned HCL and sodium hydroxide in BMR. As our formulation is stable and upon manufacturing the pH comes in limit as defined, and we do not require HCl or Sodium hydroxide for pH adjustment.
5.	Justify why the pharmaceutical equivalence studies were conducted against the comparator product instead of using innovator / reference product. Further justify why pharmaceutical equivalence does not include all quality tests.	Pharmaceutical equivalence study was done against Nezkil of continental pharma as mentioned in DRAP 293rd meeting we can use Reference or comparator product for comparison and comparator product is among brand leaders in Pakistan.
6.	The pH of the product mentioned in section 3.2.P.2.6 is 6.12 with a range of 5.0 to 7.0 which is contrary to the limit defined in your	It was a typo error. Actual pH range is 4.4 to 5.5 and our results fall in it.

	speifications. Justification is required in this regard.	
7.	Justify why terminal sterilization is not performed for the said product although being the method of choice for sterilization.	Firm has submitted that they have performed terminal sterilization and have also submitted copy of BMR.
8.	Justify why the test for filled volume is not specified in the specifications of the drug product although this test is recommended in general monograph of official pharmacopoeia.	Filled volume test reports are now provided by the firm.
9.	Justify the pH of the drug product from 4.4 to 5.5 since the pH range recommended by the innovator's product is 4.4-5.2.	Linezolid infusion batches kept on stability have pH almost in the range of 4.4 to 4.8, and this is in limit of 4.4 to 5.2, However we will revise the pH limit as according to innovator specs and will revise the testing SOP.
10.	Justify the analytical method for assay testing of the drug product which is based on UV method since the innovator's product as well as the drug substance manufacturer specify HPLC method for assay test.	Firm has submitted revised analytical procedures of the drug product dated 13-09-2021. As per the method, buk product is tested by UV method while filled vial are tested using HPLC method. **The revised method is signed on 13-09-2021 while the stability studies were initiated on December 2017.**
11.	The container closure system of the innovator is "flexible plastic infusion bags in a foil laminate overwrap" while your prduct is packed in glass vial. Justify how your container closure system can prevent the product from exposure to the light.	Stability is done in glass vial and it is stable. Also our glass vials are wrapped in laminated foil.
12.	Justify why the test of pH is not performed during stability studies.	pH is not included in stability summary sheets, however all testing is performed and mentioned in analysis certificates. pH results added in stability summary sheet.

Decision of 320th meeting of Registration Board:

Deferred for following:

- Scientific justification for revised analytical procedures of the drug product dated 13-09-2021 in which buk product is tested by UV method while filled vial are tested using HPLC method.
- Scientific justification how a revised method dated 13-09-2021 can represent the results of the stability studies which were initiated in December 2017.

Submission by the firm:

Sr. No.	Reason for deferment	Response by the firm
1.	Scientific justification for revised analytical procedures of the drug product dated 13-09-2021 in which buk product is tested by UV method while filled vial are tested using HPLC method.	Testing of bulk batch is not regulatory requirement so its testing is performed on UV (already validated method), because after bulk testing product is released for filling while finished product is tested on HPLC and product released for packing after HPLC test.
2.	Scientific justification how a revised method dated 13-09-2021 can represent the results of the stability studies which were initiated in December 2017.	As this product is not phrmacopoeial so previously batches were tested according to UV method hence the submitted stability were tested according to previous methods. Then we shifted to HPLC method effectively from 13-09-2021 for which we have revised our SOPs.

Decision: Approved with Innovator's specifications.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit fee 7,500/- for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Firm shall submit data of HPLC testing on recently manufactured batches of the applied drug product before issuance of Registration letter.**

740.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**

	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of DML number 000927 issued dated 04-06-2021 with effect from 19-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML by way of formulation to M/s Nagarsons Pharmaceuticals dated 07-06-2021 for following sections: 1. Tablet (General) 2. Tablet (Psychotropic) 3. Capsule (General) 4. Cream /ointment/Lotion/Gel
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7370: 16-03-2022
	Details of fee submitted	PKR 30,000/-: 21-02-2022
	The proposed proprietary name / brand name	**AZONAG 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin (as dihydrate)……250mg
	Pharmaceutical form of applied drug	White to off white film coated tablet
	Pharmacotherapeutic Group of (API)	Macrolides
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**USFDA** Approved)
	For generic drugs (me-too status)	Orzit Tablet 250mg of M/s Martin Dow (Reg # 057294)
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceutical Co. Ltd No. 9 Xingye Street, Shijiazhuang Economic and Technological Development Zone, Hebei Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in USP for their product against the reference product i.e. Zetamax 250mg Tablet of M/s Pfizer Pakistan. Firm has submitted results of CDP in three dissolution medium for their product against the reference product i.e. Zetamax 250mg Tablet of M/s Pfizer Pakistan.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Guolong Pharmaceutical Co. Ltd No. 9 Xingye Street, Shijiazhuang Economic and Technological Development Zone, Hebei Province China.		
API Lot No.	210507019		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	08-2021	08-2021	08-2021

Date of Initiation	26-08-2021	26-08-2021	26-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nagarsons Pharmaceutical is a new license facility hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Drug Manufacturing License of Hebei Guolong Pharmaceutical Co. Ltd. (No. JI20150058) issued by Hebei Provincial Drug Administration dated 22-07-2020. The certificate is valid till 21-07-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 10Kg Azithromycin dihydrate cleared dated 24-08-2021. The invoice is cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with UV spectra, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC systems are not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted drug substance specifications and analytical method from both API manufacturer as well as Nagarsons Pharma.
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Firm has submitted report of verification studies of the analytical method of drug substance.
3.	Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product.	Firm has submitted COA of relevant batch of drug substance from API manufacturer as well as Nagarsons Pharma.
4.	Justify why pharmaceutical equivalence and CDP studies are performed against zetamax tablet of Pfizer instead of using the innovator's product.	We use Zetamax tablet by Pfizer because the innovator product is not available in the market in Pakistan.
5.	Provide raw data sheets for the calculation of results of dissolution test throughout the stability studies.	Firm has submitted raw data sheets for the calculation of results of dissolution test throughout the stability studies using HPLC method.
6.	Provide evidence of column oven which is required to maintain temperature of 50°	Firm has not submitted evidence of HPLC along with column oven.
7.	Submit Batch Manufacturing Record of three stability batches.	Firm has submitted copy of Batch Manufacturing Record of three stability batches.

Decision of 320th meeting of Registration Board:

Deferred for submission of evidence of HPLC system along with column oven which is required to maintain temperature of 50° for assay testing of drug product as per USP monograph.

Response by the firm:

Firm has submitted following documents:

- Copy of invoice from Prestigious Multi Enterprises for purchase of HPLC dated 12-01-2021.

- Firm has also submitted another copy of invoice from Prestigious Multi Enterprises dated 12-01-2021 for purchase of HPLC column c-18 along with HPLC Column Oven.
- Firm has also submitted caliberation certificate from Galvano Scientific (Pvt) Ltd dated 12-04-2022 for caliberation of HPLC including its column oven set at 40 degree.
- Picture of an HPLC system with column oven set at 50 degree claimed to be placed in their QC lab.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit IQ, OQ and PQ of HPLC system along with column oven before issuance of registration letter.**

741.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of DML number 000927 issued dated 04-06-2021 with effect from 19-02-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML by way of formulation to M/s Nagarsons Pharmaceuticals dated 07-06-2021 for following sections: 1. Tablet (General) 2. Tablet (Psychotropic) 3. Capsule (General) 4. Cream /ointment/Lotion/Gel
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7372: 16-03-2022
	Details of fee submitted	PKR 30,000/-: 21-02-2022
	The proposed proprietary name / brand name	**AZONAG 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin (as dihydrate)……500mg
	Pharmaceutical form of applied drug	White to off white film coated tablet
	Pharmacotherapeutic Group of (API)	Macrolides
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**USFDA** Approved)

	For generic drugs (me-too status)	Azomax Tablet 500mg of M/s Novartis Pakistan (Reg # 045415)
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceutical Co. Ltd No. 9 Xingye Street, Shijiazhuang Economic and Technological Development Zone, Hebei Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in USP for their product against the reference product i.e. Azomax 500mg Tablet of M/s Novartis Pakistan. Firm has submitted results of CDP in three dissolution medium for their product against the reference product i.e. Azomax 500mg Tablet of M/s Novartis Pakistan.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Hebei Guolong Pharmaceutical Co. Ltd No. 9 Xingye Street, Shijiazhuang Economic and Technological Development Zone, Hebei Province China.		
API Lot No.	210507019		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	26-08-2021	26-08-2021	26-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nagarsons Pharmaceutical is a new license facility hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Drug Manufacturing License of Hebei Guolong Pharmaceutical Co. Ltd. (No. JI20150058) issued by Hebei Provincial Drug Administration dated 22-07-2020. The certificate is valid till 21-07-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 10Kg Azithromycin dihydrate cleared dated 24-08-2021. The invoice is cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with UV spectra, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC systems are not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted drug substance specifications and analytical method from both API manufacturer as well as Nagarsons Pharma.
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Firm has submitted report of verification studies of the analytical method of drug substance.

3.	Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product.	Firm has submitted COA of relevant batch of drug substance from API manufacturer as well as Nagarsons Pharma.
4.	Submit stability study data in proper sequence as per the guidelines of registration Board since the submitted data is not properly aligned.	Firm has submitted complete data in section 3.2.P.8.3 as per the guidelines specified in CTD guidance document.
5.	Provide raw data sheets for the calculation of results of dissolution test throughout the stability studies.	Firm has submitted raw data sheets for the calculation of results of dissolution test throughout the stability studies using HPLC method.
6.	Provide evidence of column oven which is required to maintain temperature of 50°	Firm has not submitted evidence of HPLC along with column oven.
7.	Submit Batch Manufacturing Record of three stability batches.	Firm has submitted copy of Batch Manufacturing Record of three stability batches.

Decision of 320th meeting of Registration Board:
Deferred for submission of evidence of HPLC system along with column oven which is required to maintain temperature of 50° for assay testing of drug product as per USP monograph.

Response by the firm:
Firm has submitted following documents:

- Copy of invoice from Prestigious Multi Enterprises for purchase of HPLC dated 12-01-2021.
- Firm has also submitted another copy of invoice from Prestigious Multi Enterprises dated 12-01-2021 for purchase of HPLC column c-18 along with HPLC Column Oven.
- Firm has also submitted caliberation certificate from Galvano Scientific (Pvt) Ltd dated 12-04-2022 for caliberation of HPLC including its column oven set at 40 degree.
- Picture of an HPLC system with column oven set at 50 degree claimed to be placed in their QC lab.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit IQ, OQ and PQ of HPLC system along with column oven before issuance of registration letter.**

742.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 25-03-2021.
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 19891: 15-07-2021
	Details of fee submitted	PKR 50,000/-: 27-04-2021
	The proposed proprietary name / brand name	**ROVITROX 2g Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……2g
	Pharmaceutical form of applied drug	Sterile white to off white / yellowish crystalline powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Rocephin injection by Roche.
	Name and address of API manufacturer.	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Firm has also submitted compatibility studies of the drug product along with the recommended diluent i.e. water for injection.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in USP for their product against the comparator i.e. Rocephin 2g Injection of M/s Roche Pakistan.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.		
API Lot No.	00421/002/2019		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	20-02-2020	20-02-2020	20-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 10Kg Ceftriaxone sodium (sterile) dated 19-02-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Firm was asked to submit the following:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.

- Submit product development and stability study data of commercial batches manufactured by the drug product manufacturer as per the decision of 312nd meeting of Registration Board, since the submitted data are of trial batches.

Response by the firm:
The firm submitted its response (Dy No. 6979) dated 14-03-2022 submitted the following data:

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China.		
API Lot No.	Q012105004		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21H043	21H044	21H045
Batch Size	10,000 vials	10,000 vials	10,000 vials
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	16-08-2021	16-08-2021	16-08-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SX20180229) issued by CFDA China dated 06-06-2018. The GMP certificate is valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-06-2021 specifying import of 150Kg Ceftriaxone sodium (sterile). The invoice was cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Firm has changed the source of drug substance from Pharmagen limited to Sinopharm Weiqida.
- Firm has submitted copy of BMR of commercial batches.
- Firm has not submitted fee for change of API source and stability study data.

Decision of 320th meeting of Registration Board:
Deferred for clarification for performing pharmaceutical equivalence studies against Rocephin Injection 2g since this product is not registered in Pakistan.

Response by the firm:
Firm has submitted as under:
Please refer to the subject cited above; we are hereby submitting the Pharmaceuticals equivalence of Rovitrox 2g Injection with Oxidil 2g Injection. Typographically mistake in Pharmaceutical equivalence Report mentioned Rocipen 2g injection instead of oxidil 2gm injection.

Firm has submitted pharmaceutical equivalence report against Oxidil 2g Injection manufactured by Sami with following product details
Batch No: 010E
Mfg. Date: 09-2019
Exp. Date: 08-2021

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

743.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Capsule section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16394: 14-06-2021
	Details of fee submitted	PKR 50,000/-: 24-07-2021
	The proposed proprietary name / brand name	**VALIXIME 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	White to off white powder filled in glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefspan suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00243/050/2020		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003

Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	21-02-2020	21-02-2020	21-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 19-02-2020 specifying purchase of 10Kg Cefixime (Micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Firm was issued letter of shortcoming for the following observations. The firm has replied to the queries and the response is as below:

Shortcomings communicated	**Response by the firm**
Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.	Firm has submitted that they will submit the differential fee before issuance of registration letter.
Submit valid contract manufacturing agreement between the contract giver and contract acceptor.	Firm has submitted contract manufacturing agreement dated 17th December 2020 between the contract giver and contract acceptor.
Submit product development and stability study data of commercial batches manufactured by the drug product manufacturer, since the submitted data are of trial batches.	Firm has submitted stability study data of 3 commercial batches and have referred to the product development studies previously submitted in the initial application. The details of the stability studies data is as follows:

STABILITY STUDY DATA OF COMMERCIAL BATCHES

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	00243/050/2020
Description of Pack (Container closure system)	Glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	21D002	21D004	21E002
Batch Size	5000 bottles	5000 bottles	5000 bottles
Manufacturing Date	04-2021	04-2021	05-2021
Date of Initiation	27-04-2021	29-04-2021	04-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC system is not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision of 316th meeting of Registration Board:
Deferred for submission of documents for procurement of drug substance which is used in the manufacturing of commercial batches of the drug product.

Submission by the firm: Firm has submitted copy of invoice dated 30-06-2021 from Pharmagen Limited specifying purchase of Cefixime (micronized) 25kg.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit differential fee 25,000/- for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.**
- **Firm shall submit full fee 75,000/- for revision of stability study data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

744.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi-75020, Pakistan.
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi-75020, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16356 Dated 14-06-2021
	Details of fee submitted	PKR 20,000/-: Dated 17-11-2020
	GMP status of the Finished product manufacturer	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
	The proposed proprietary name / brand name	Rebamide 100mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Rebamipide…….100mg
	Pharmaceutical form of applied drug	White round biconvex tablet coated plain on both sides.
	Pharmacotherapeutic Group of (API)	Gastro-protective drug
	Reference to Finished product specifications	JP specifications
	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mucosta Tablets 100mg of M/s Otsuka Pharmaceutical Co., Ltd (PMDA approved)
	For generic drugs (me-too status)	Mucosta 100mg tablet by Otsuka (Reg # 078129)
	Name and address of API manufacturer.	M/s Jiangxi synergy pharmaceutical, Co., Ltd Jiangxi fengxin Industrial part, fengxin, Jiangxi province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Rebamipide is present in JP. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ±2˚C /65% ±5%RH for 60 months Accelerated: 40˚C ±2˚C / 75% ±5%RH for 6 months Batches: (20100704, 20100705, 20100706)

	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against innovator product Mucosta 100mg tablet (batch # 7B79MT3) by Otsuka Pharmaceutical Co., Ltd by performing quality tests (Physical appearance, thickness, hardness, disintegration, Dissolution, Assay). CDP has been performed with Mucosta 100mg Tablet by otsuka Pharma in acidic media (pH 0.1N HCl) & Phosphate Buffer (pH 6.8, 4.5, 6.0). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, LOD, LOQ)

STABILITY STUDY DATA			
Manufacturer of API	M/s Jiangxi synergy pharmaceutical, Co., Ltd, Jiangxi fengxin industrial part, fengxin, Jiangxi province, P.R.China		
API Lot No.	05-20170201C		
Description of Pack (Container closure system)	Alu / PVC Blister pack (10's, 20's, 30's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	01-2018	11-2018	11-2018
Date of Initiation	07-02-2018	07-12-2018	09-12-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of previous inspection report of Rofair 500 mcg Tablet which is conducted on 25-06-2019. The report confirms that: HPLC system is 21 CFR part II compliant. Digital data logger was present.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of DML No. GAN 20160125 issued by Jiangxi province FDA valid till 15-02-2021. The firm has submitted copy of GMP certificate (No. 2017001) issued by Jiangxi CCD valid till 23-07-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of Form 6 license no. 2782 cleared by AD (I & E) DRAP, dated 12-10-2017. However, invoice is not attested.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

Sr. No.	Observations communicated	Response by the firm
1.	Copies of the Drug substance specifications and analytical procedures used for routine testing of the drug substance / active pharmaceutical ingredient by both drug substance & drug Product manufacturer.	The firm has submitted copies of drug substance specifications and analytical procedures from both drug substance manufacturer and drug product manufacturer.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report of Rebamipide by titration method.
3.	COA of primary / secondary reference standard including source and lot number shall be provided.	The firm has submitted copy of CoA of working standard of Rebamipide (lot # 201639).
4.	List of all components of the dosage form, and their amount on a per unit basis, the function of the components, and a reference to their quality standards (e.g. compendial monographs or manufacturer's specifications) shall be submitted.	The firm has submitted qualitative and quantitative composition alongwith function of components and reference to their quality standards.
5.	Details of batch numbers of reference product and test formulation used for Pharmaceutical equivalence are required.	Details of pack of innovator product Mucosta Tablet 100mg (Batch # 7B79MT3) of M/s Otsuka pharmaceutical Co., Ltd have been submitted.
6.	The results of analytical method verification studies need to be summarized in tabulated form for each parameter since only chromatograms are presented for each parameter.	The firm has provided summarized tabulated results for linearity, accuracy, precision and specificity.
7.	The copies of complete analysis of at least two batches shall be provided.	Batch analysis of two batches of Rebamipide tablet 100mg were provided.
8.	Those impurities that are degradation product shall be included in the specifications.	Details of related substances were included in finished product specifications.
9.	Justification of specification of non-pharmacopeial product shall be based on batch analysis results.	Since the monograph of Rebamipide Tablet 100mg is available in Japanese pharmacopoeia. Therefore, no justification of specifications is required.
10.	Description of the primary container closure systems shall be submitted.	The firm has provided specifications of PVC film clear transparent and Aluminium Foil Blister.
11.	The results of stability data of B. No.: 002 (TF-02) are lying borderline limit of 95% at 18 months. Result of 24-month stability time point is not submitted.	The firm has submitted 6-month accelerated and 24-month real time stability study data of applied product. The assay result of 24-month time point is

		95.09% for B. No. 002 which is lying at borderline limit of 95% -105%.
12.	Submitted chromatograms do not reflect the UV detector wavelength at which analysis has been conducted.	Details of UVProbe software containing wavelength of 326 nm have been provided.
13.	The submitted copy of DML is expired and submitted copy of GMP certificate is not issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Jiangxi Synergy Pharmaceutical Co., Ltd, china issued by Jiangxi Food and Drug Administration. The certificate is valid till 23-07-2022.
14.	Documents for the procurement of API with approval from DRAP including commercial invoice.	The firm has submitted copy of invoice for the import of Rebamipide JP17 (260g) dated 18-07-2017 received through DHL courier. The invoice is not cleared by AD (I&E) of field office.

Previous Decision: Deferred for submission of any document confirming that material (Rebamipide (260g)) has been imported and cleared by Custom authorities against the submitted invoice.
Evaluation by PEC: The firm has submitted copies of Form-6 and invoice for the purchase of Rebamipide JP (Quantity: 260mg, invoice no. JXSS170718) from M/s Jiangxi Fengxin pharmaceutical Co. Ltd., China attested by Assistant Director (I&E) DRAP, Karachi dated 17-10-2017.

Decision of 317th meeting of Registration Board:
Registration Board decided to defer the case and referred both invoices to DRAP Karachi for verification from record since 1st submitted invoice was without attestation/clearance from DRAP Karachi.

Evaluation by PEC:
The case along with copy of invoice, Form 6 and Decision of 317th meeting of Registration Board was forwarded to Additional Director DRAP Karachi office through e-office file number "copy-of-31/2022-PEC-002" by Incharge PEC on 18-08-2022. The status of the invoice has been verified with following remarks:
"*Respected Sir,*
with refer to Para- 2/N Form-6 and invoice has been checked from available office records and it is verified that the same has been issued from this office further the copies are also attached for ready reference, please"
The case is submitted for consideration by the Board.

Decision: Approved.

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

745.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Inspection report dated 24-01-2018 concludes very good level of cGMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 27-07-2015 specifying Tablet General section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 23542: 12-11-2019
	Details of fee submitted	PKR 50,000/-: 12-11-2019
	Proposed proprietary name / brand name	CONOFEN Tablet 10/200mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Phenylephrine HCl……10mg Ibuprofen……..200mg
	Pharmaceutical form of applied drug	Light brown colored film coated tablet, oval (Biconvex) with bisect line on one side and plain on other side
	Pharmacotherapeutic Group of (API)	NSAID in combination with sympathomimetic amine
	Reference to Finished product specifications	Manufacturer's specs
	Proposed Pack size	10's, 20's, 30's, 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Advil Congestion Relief Tablet 200mg/10mg (USFDA Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Phenylephrine HCl:** Shenzhen oriental pharmaceutical Co. Ltd. #43, Dakeng Road, Tongle Village, Longgang District Shenzhen China. **Ibuprofen:** Zenith Chemical Industries (Pvt) Limited. MozaDhonday, JiaBaga Raiwind-Kahna Road, Raiwind Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Firm has submitted DMF for both drug substances including their stability study data.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both API at accelerated and real time conditions. The real time stability data is conducted as per zone IV-A conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and

		stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has not submitted data of pharmaceutical equivalence as well as comparative dissolution profile
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA			
Manufacturer of API	**Phenylephrine HCl:** Shenzhen oriental pharmaceutical Co. Ltd. #43, Dakeng Road, Tongle Village, Longgang District Shenzhen China. **Ibuprofen:** Zenith Chemical Industries (Pvt) Limited. MozaDhonday, JiaBaga Raiwind-Kahna Road, Raiwind Pakistan.		
API Lot No.	**Phenylephrine HCl:** PEH-180101Y1 **Ibuprofen:** ZIBU18-009		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1500 tablet	1500 tablet	1500 tablet
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	02-02-2019	02-02-2019	02-02-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last inspection report for their product "saferon tablet " Registration Board in its 278th meeting decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad. Date of Inspection: 10-12-2015 , 19-04-2017 & 20-01-2018 • Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Phenylephrine HCl:** Copy of GMP certificate (No. GD20150448) issued by CFDA china is submitted by the firm. The certificate is valid till 07-12-2020. **Ibuprofen:** Copy of GMP certificate of M/s Zenith Chemical Industries (Pvt) Limited dated 22-05-2019 issued on the basis of inspection dated 06-12-2018 is submitted by the firm. The certificate is issued by Additional Director DRAP Lahore.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Phenylephrine HCl:** Firm has submitted copy of commercial invoice specifying import of 308.25g of phenylephrine dated 10-05-2018. The invoice is signed by AD (I&E) DRAP Islamabad.

		Ibuprofen: Firm has submitted copy of invoice specifying purchase of 250Kg Ibuprofen from Zenith Chemical Industries Lahore dated 26-06-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

Shortcomings communicated	**Response by the firm**
Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "*Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation & the innovator / reference / comparator product should be submitted and discussed*."	Pharmaceutical equivalence dissolution study has not been performed due to non-availability of reference product in local market (Pakistan) and it is difficult to arrange. However, we are committed to conduct / perform pharmaceutical equivalence of reference product as available and will submit the requisite data.
Submit summary of the results of comparative dissolution profile in section 3.2.P.2.2.1. to comply the decision of 293rd meeting of Registration Board, which states that "*The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed. For comparative dissolution profile, the guidelines specified in WHO Technical Report Series No. 992, 2015, Annex 7, Appendix 1 Recommendations for conducting and assessing comparative dissolution profiles and USFDA Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms - Dissolution Profile Comparisons may be followed".*	Comparative dissolution study has not been performed due to non-availability of reference product in local market (Pakistan) and it is difficult to arrange. However, we are committed to conduct / perform pharmaceutical equivalence of reference product as available and will submit the requisite data.
Scientific rationale for development of tablet having bisect line on one side of the tablet.	Our applied Drug products (Conofen Tablets 5/200mg and Conofen Tablets 10/200mg) compressed on oval (bi-convex) shaped having bisect line on one side and plain on other side which is our available punch design and the applied drug products are stable with afore mentioned punch design. Moreover, we had submitted the stability studies data of three batches (Trials) on accelerated and real-Time stability conditions (as per decision of 293rd meeting of Drug Registration Board.
Provide acceptance criteria in terms of the amount of dissolved active ingredient "Q" for dissolution test at 15 minutes.	Acceptance criteria in terms of the amount of dissolved active ingredient Q = NLT 80% for dissolution test of conofen tablets at 15minutes for both Phenylephrine HCL and Ibuprofen.

Decision of 296th meeting of Registration Board:

Deferred for following submissions:

- Pharmaceutical equivalence data of the applied product along with innovator / reference or comparator product.
- Comparative Dissolution Profile (CDP) data of the applied product along with innovator / reference or comparator product.

Response by the firm:

Reason for deferment	Response by the firm
Pharmaceutical equivalence data of the applied product along with innovator / reference or comparator product.	Firm has submitted results of pharmaceutical equivalence of their product against the reference product Advil Tablet. Manufacturer: Pfizer Madison NJ USA Batch No: R86956 Exp Date: 06/2023
Comparative Dissolution Profile (CDP) data of the applied product along with innovator / reference or comparator product.	Firm has submitted results of Comparative Dissolution Profile (CDP) of their product against the reference product Advil Tablet in three dissolution medium as recommended by WHO guidelines. Manufacturer: Pfizer Madison NJ USA Batch No: R86956 Exp Date: 06/2023

Decision of 313rd meeting of Registration Board:

Deferred for following:

- Updated GMP status of the firm from QA&LT Division DRAP.
- Submission of fee for revision of specifications of the drug product.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Updated GMP status of the firm from QA&LT Division DRAP.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022.
2.	Submission of fee for revision of specifications of the drug product.	Firm has submitted copy of fee challan (Number: 77974410916) for change in specifications for amount 7,500/- dated 22-08-2022.

Decision: Approved with Innovator's specifications.

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

746	Name, address of Applicant / Marketing Authorization Holder	M/s World Biz Pharmaceutical Company, Plot No. 340, Multan Industrial Estate, Multan.
	Name, address of Manufacturing site.	M/s World Biz Pharmaceutical Company, Plot No. 340, Multan Industrial Estate, Multan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of DML number 000942 issued on 13-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 specifying Oral liquid syrup section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 22536: 10-08-2022
	Details of fee submitted	PKR 30,000/-: 09-06-2022
	The proposed proprietary name / brand name	**Para Biz Suspension 120mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Paracetamol ……120mg
	Pharmaceutical form of applied drug	Oral suspension
	Pharmacotherapeutic Group of (API)	Analgesic / antipyretic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Junior Paracetamol Suspension (**MHRA** Approved)
	For generic drugs (me-too status)	Calpol suspension of M/s GSK Pakistan (Reg # 000354)
	Name and address of API manufacturer.	M/s Zenith Chemical Industries (Pvt) Limited. 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore - Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in BP for their product

		against the reference product i.e. PANADOL suspension of GSK Pakistan (Pvt) Ltd.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zenith Chemical Industries (Pvt) Limited. 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore - Pakistan		
API Lot No.	ZPAR20-350		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-AS-001	RD-AS-002	RD-AS-003
Batch Size	2000 Bottle	2000 Bottle	2000 Bottle
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	15-11-2021	15-11-2021	15-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Zenith Chemical Industries is issued by DRAP on 22-05-2019. The certificate is issued based on the inspection dated 06-12-2018.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with UV spectra, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC systems are not 21 CFR compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine

testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."

- Provide verification studies of drug substance from drug product manufacturer.
- Specifications are mentioned as BP in some sections and USP in other sections.
- Assay method is based on HPLC while verification studies are conducted on UV method.
- Analytical method specifies HPLC method, while assay testing in stability studies is conducted on UV
- Provide copy of commercial invoice for evidence of purchase of the drug substance.

Decision of 320th meeting of Registration Board:

Deferred for;

- Submission of data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submission of verification studies of drug substance from drug product manufacturer.
- Clarification since specifications are mentioned as BP in some sections and USP in other sections.
- Clarification regarding the assay method which is based on HPLC while verification studies are conducted on UV method.
- Clarification since analytical method specifies HPLC method, while assay testing in stability studies is conducted on UV
- Submission of copy of commercial invoice for evidence of purchase of the drug substance.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of specifications of the drug substance from drug product manufacturer as well.
2.	Submission of verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
3.	Clarification since specifications are mentioned as BP in some sections and USP in other sections.	Applied product is of BP specifications.
4.	Clarification regarding the assay method which is based on HPLC while verification studies are conducted on UV method.	We have adopted alternate method in which assay is based on UV method for stability of batches for CTD purpose. After registration we will adopt pharmacopoeia method and will verify it as per ICH guidelines.
5.	Clarification since analytical method specifies HPLC method, while assay testing in stability studies is conducted on UV	We have adopted alternate method in which assay is based on UV method for stability of batches for CTD purpose. After registration as per undertaking we will adopt pharmacopoeial method for process validation and both accelerated and long term stability studies of commercial batches.
6.	Submission of copy of commercial invoice for evidence of purchase of the drug substance.	Firm has submitted copy of commercial invoice dated 29-10-2021 specifying purchase of 10Kg paracetamol.

Decision of 321st meeting of Registration Board:

The Board discussed that the official monograph of the applied product is present in B.P whereas the firm has performed the testing according to In-House specifications. The Board decided to defer the case for submission of testing of the applied product according the monograph available in B.P along with the analytical method verification studies for the drug product on the next month time point of long term stability studies for all the 03 stability batches.

Submission by the firm:

Firm has submitted following documents:

• Copy of method verification studies of the applied product according to BP monograph. • 9 months stability study data at real time conditions for three batches conducted as per BP monograph along with analytical record.
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

747.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25 Sector 20, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 21-01-2021 is submitted.
	GMP status of the firm	**Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000783 of M/s Stallion Pharma Islamabad dated 08-02-2016 specifying dry powder injection Vial (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7086: 03-03-2021
	Details of fee submitted	PKR 70,000/-: 19-01-2021
	The proposed proprietary name / brand name	**ASPINEM 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical

		Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 500mg Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
API Lot No.	1705205135 1705205096 1705203623
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T7003	T7004	T7005
Batch Size	7800 vials	7800 vials	7570 vials
Manufacturing Date	09-2017	10-2017	11-2017
Date of Initiation	25-09-2017	13-11-2017	16-11-2017
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

- Firm has submitted fee 70,000 for the application of contract manufacturing

Shortcomings communicated	**Response by the firm**
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of analytical method of drug substance from the drug product manufacturer. The analytical method is issued on 20-07-2021.
Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	Firm has submitted report of verification studies of the analytical method of drug substance. However, the verification studies were conducted on 21-01-2021 while the analytical method of drug substance was issued by the drug product manufacturer on 20-07-2021.
Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product	Firm has submitted COA of the drug substance generated by drug product manufacturer only, while the COA of drug substance manufacturer is not submitted.

manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".	
Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug substance and drug product.	Firm has submitted COA of working standard from drug substance manufacturer which has been standardized against USP reference standard. However drug product manufacturer is using working standard of meropenem Batch No. SI/MPM/00060120 manufactured by M/s Sterile India.
Justify the master formulation containing 570mg of meropenem trihydrate for manufacturing of 500mg meropenem for injection, since the drug substance contains meropenem blended with 15.10 to 16.50% w/w of sodium carbonate.	Firm has submitted calculation to justify the filled weight. As per calculations submitted by the firm the weight 570mg per vial is calculated on theoretical basis considering that the drug substance has 100% assay, while the actual dispensing is to be made on the basis of actual % assay of the meropenem.
Justify the use of 5% overage in the formulation, since the justification submitted in this regard is not supported by any guidelines.	We hereby justify that in development stage we added 5% extra meropenem sterile powder for injection in initial batches. After completion of stability study degradation is no more than 2 – 3% within the limit assay range is 90 – 120% so no more 5% meropenem sterile powder for injection is added.
Submit results of compatibility studies in section 3.2.P.2.6.	Firm has submitted result of compatibility studies of the drug product with WFI.
Justify how the time and temperature of sterilization cycle is directly selected without any protocols for its validation.	Firm has submitted summary report of autoclave machine re qualification instead of providing justification.
Provide detailed method of sample stock solution preparation instead of mentioning the general statement "Constitute a container of Meropenem for Injection with a volume of water, corresponding to the quantity of solvent specified in the labelling".	Firm has not submitted complete method of analysis of the drug product in which the method of sample solution preparation is explained.
Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	Firm has submitted that we are using potency of working standard as percentage. USP taking the potency in mg/mg which is converted into percentage by multiplying this ratio with 100. Firm has submitted calculation to justify that their formula is equivalent to USP. However, the USP formula used by the firm is different from that specified in USP.
Analytical method verification studies have not been conducted and evaluated in the light of USP general chapters and ICH guidelines.	Firm has submitted verification studies of the analytical method dated 21-01-2021, while the analytical method of the drug product was revised and updated on 12-07-2021.
Justify why the drug product specifications does not contain the test for sodium contents as recommended by USP.	In Meropenem trihydrate injection label claim is as meropenem while trihydrate and sodium considered as impurity. We are verifying the meropenem by HPLC and due to unavailability of the atomic absorption we were verifying the sodium content by titration method. Moreover, for verification purpose, we analysed sodium content from PCSI and Citi Pharma with atomic absorption. And now we have atomic absorption in our facility and we have changed our SOP accordingly and now we are conducting each and every analysis of sodium content in our facility as per USP monograph.
Justify the test of accuracy in analytical method validation without specifying the concentrations of the solution which are analysed for accuracy. Further justify the use of solutions having low, medium, and high concentration of sample without specifying their exact	Firm has submitted that we had performed the accuracy by making a concentration of standard preparation and three concentrations. The concentrations used by the firm for accuracy test is 0.16mg/ml, 0.20mg/ml and 0.24mg/ml.

concentration. Such words are not recommended by any scientific guidelines.	As per the analytical method the standard solution concentration is 0.11mg/ml and the concentration used by the firm to study accuracy does not include the said concentration.
Linearity and range have been studied from 70% to 120% of the solution wherein the area under curve for 100% solution was 4691449 while in accuracy studies in the same method none of the solution (either low, medium or high concentration) achieved such area although the concentration of the solution is expected to be the same. Justification is required in this regard.	Two different samples were prepared for linearity and accuracy parameter of analytical method verification, for linearity parameter from the first dilution 6 further second dilutions 70%, 80%, 90%, 100%, 110% and 120% were prepared while in accuracy 3 further second dilutions low, medium and high were prepared. Because the weights of the sample are different in linearity and accuracy parameters that's why the area achieved is different for both parameters.
In linearity studies the area under curve for 100% solution was 4691449, while in stability studies the area under curve of the sample solution having exactly same concentration is reported to be 11769485. Justification is required in this regard how such huge difference in area under the curve can exist in the analysis and how this method can be considered reliable and verified.	In linearity the sample solution preparation is different from the sample preparation of finished product. In linearity a concentration of standard taken to prepare first dilution then make second dilution by taking 7ml, 8ml, 9ml, 10ml, 11ml, 12ml from the first dilution, second dilution of 10ml is considered as 100% concentration while in finished good the dilution contain 100mg of sample that's why area under curve for 100% solution is different from the area of 100mg in finished product.
The analytical method verification studies have been conducted in January 2021 while the batches were manufactured in 2017. Justification is required in this regard.	In 2017, we had completed analytical method verification by performing three parameters which are linearity, system suitability and specificity while when we submit the CTD dossier we came to know the DRAP requirement of accuracy and repeatability, then we had complete the analytical method verification by performing five parameters which are linearity, system suitability, specificity accuracy and repeatability.
Justify the limit of sodium content in the in house generated COA of drug substance, in which limit of sodium content is taken as 6.0% to 9.3% and the drug substance was passed on the basis of results of 9.12%, while the drug substance manufacturer specifies the limit of sodium content as 6.56% to 7.20%.	In past we were doing sodium content analysis by titration method (due to unavailability of AAS) the result was 9.12% limit of sodium content is 6.0% - 9.3% while the drug substance manufacturer specifies the sodium content as 6.65 to 7.20%. Now we are doing sodium content with AAS according to USP.
As per the submitted results of sodium content in meropenem injection by CITI Pharma, the results of % sodium content is 7.867%, while USP specifies the acceptance criteria to be 80%–120% of the labeled amount of sodium. Justify how your results complies USP specifications keeping in view the labelled amount of sodium in your product.	Firm has not submitted any justification
Justify the use of commercial lot of meropenem for injection as working standard since USP recommends that reference standard should be pure meropenem trihydrate.	The assay of meropenem trihydrate USP reference standard lot# J0K434, is 87.3% meropenem. Similarly by comparing with reference standard we prepare our meropenem trihydrate working standard in which 82.12% is meropenem present. Actually the material used in USP Reference standard and the working standard is the same as meropenem trihydrate because the product label claim is meropenem, therefore we have to calculate the assay against the purity of material as meropenem which is 87.3% in USP Reference standard and 82.12% in working standard.
Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has not submitted details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Further documents confirming import of these relevant batches are also required.
Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point, since the	Firm has not yet submitted stability study data in proper sequence with COA for each time point, raw data sheets and chromatograms. Raw data sheets are not submitted. Further the calculation formula used for the calculation

submitted chromatograms and analytical reports are without any proper sequence.	of assay result is also different from USP as well as the method of sample and standard solution preparation.
Provide Reference of previous approval of applications with stability study data of the firm (if any)	No response submitted by the firm
Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.	No response submitted by the firm
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	No response submitted by the firm

Decision of 316th meeting of Registration Board:

Deferred for following:

- Submission of differential fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.
- Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.
- Scientific justification for use of 5% overage in the formulation.
- Submission of complete protocols of process validation studies of the drug product.
- Submission of detailed method of analysis of the drug product with details of sample solution preparation.
- Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.
- Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.
- Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of differential fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has submitted differential fee 5,000/- vide slip number 551237597908 dated 20-05-2022.
2.	Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.	Firm has submitted COA of relevant batch of drug substance generated by drug substance manufacturer.
3.	Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.	This firm has submitted that the assay of Meropenem Trihydrate USP reference standard lot # J0k434 is 87.3%. Therefore, we used sterile India material as working Standard having potency 82.02% by using standardization procedure with USP reference standard. Material used for batch manufacturing is from Aurobindo China and working standard prepared is of Sterile India having Potency 82.02% COA's for Reference standard & working standard along with standardization procedure is submitted by the firm.
4.	Scientific justification for use of 5% overage in the formulation.	Firm has submitted that an overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra

		quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
5.	Submission of complete protocols of process validation studies of the drug product.	Firm has submitted general protocols for process validation. **Firm has not submitted specific protocols for the process validation of applied product.**
6.	Submission of detailed method of analysis of the drug product with details of sample solution preparation.	Firm has submitted detailed method of analysis of the drug product, **However in the submitted method, sample solution preparation method is still not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions.** Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
7.	Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.	Firm has submitted that they are using the potency of working standard as percentage. USP taking the Potency into mg/mg which is covered into percentage multiplying the ratio with 100 so there is no difference between the USP formula & our standard operating formula further more we have amended our SOP with respect to the formula given in USP. **However, the newly used calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard. The new formula is also not exactly as per USP monograph.**
8.	Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has now added sodium content test in their specifications. Firm has also submitted fee 7,500/- vide slip number 212267176 dated 20-05-2022. **However, no data regarding the sodium content testing during stability studies is provided.**
9.	Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.	Firm has not justified the previous validation reports, instead the firm has submitted new report in which the analysis is carried out on July 2022. The new report was performed in line with ICH recommendations.
10.	Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.	Firm has submitted data in section 3.2.P.8.3. The evaluation os submitted data is as under:

Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
Documents for the procurement of API with approval from DRAP (in case of import).	**1705205135, 1705205096:** Firm has submitted copy of commercial invoice cleared dated 19-10-2017 specifying import of 20Kg meropenem for lot number 1705205135, 1705205096. The invoice is cleared by AD (I&E) DRAP. **1705203623:**

		Firm has submitted copy of commercial invoice cleared dated 12-09-2017 specifying import of 15Kg meropenem for lot number 1705203623. The invoice is cleared by AD (I&E) DRAP.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of product testing including HPLC chromatogram and raw data sheets
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for stability chambers for accelerated and real time stability study.

Decision of 320th meeting of Registration Board:

Deferred for following:

- Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.
- Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
- Submission of specific protocols for the process validation of applied product.
- Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
- Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.	An overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
2.	Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.	Capacity assessment report is not yet received.
3.	Submission of specific protocols for the process validation of applied product.	Firm has submitted process validation protocols
4.	Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard	Firm has submitted revised testing method and specifications dated 30-09-2022. The revised method is again unclear about the sample solution preparation method since it is not clear in terms of exact volume of water used to reconstitute the contents of vial.

	while USP recommends to use concentration of sample and standard.	
5.	Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.	Firm has submitted revised testing method and specifications dated 30-09-2022. The formula used for calculation of assay of drug product is different from USP since USP recommends concentration of sample and standard solution while the firm is using weight of sample and standard solution. Firm has again submitted another revised testing method and specifications dated 23-11-2022 in which the testing method is as per USP monograph along with test for sodium contents.

Proceedings & Decision: Registration Board was apprised that the applied formulation has already been approved in 312th meeting opf Registration Board for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, wherein following submission had also been made by the firm and above mentioned points have been addressed and responded:

1. **Evidence for purchase of atomic absorption spectrophotometer in the form of purchase order dated 14-06-2021, deliver challan dated 19-06-2021 & invoice No. 06/3029 dated 18-06-2021.**
2. **Installation and operational qualification reports of atomic absorption spectrophotometer**
3. **Analysis report of Sodium Content in Mopen (Meropenem) Injection by M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**

On basis of above cited reference Registration Board decided to approve instant application. Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**

748.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25 Sector 20, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 21-01-2021 is submitted.
	GMP status of the firm	**Stallion Pharmaceuticals:** Firm has submitted GMP certificate issued on the basis of inspection dated 22-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000783 of M/s Stallion Pharma Islamabad dated 08-02-2016 specifying dry powder injection Vial (carbapenem) section.
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7087: 03-03-2021
	Details of fee submitted	PKR 70,000/-: 19-01-2021
	The proposed proprietary name / brand name	**ASPINEM 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……1g (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White or almost white, hygroscopic, crystalline, powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols,

		control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 1g Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurobindo Pharma Limited Unit-V, Plot No. 68-70, 73-91, 95, 96, 260, 261 I.D.A Chemical Zone, Pashamylaram, Patancheru Mandal, Sanga Reddy District Telangana, India.		
API Lot No.	1705205135 1705205096 1705203623		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	U7003	U7004	U7005
Batch Size	3900 vials	7600 vials	3780 vials
Manufacturing Date	09-2017	10-2017	11-2017
Date of Initiation	04-10-2017	14-11-2017	17-11-2017
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Evaluation by PEC:

- Firm has submitted fee 70,000 for the application of contract manufacturing

Shortcomings communicated	Response by the firm
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted copy of analytical method of drug substance from the drug product manufacturer. The analytical method is issued on 20-07-2021.
Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	Firm has submitted report of verification studies of the analytical method of drug substance. However, the verification studies were conducted on 21-01-2021 while the analytical method of drug substance was issued by the drug product manufacturer on 20-07-2021.
Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification)".	Firm has submitted COA of the drug substance generated by drug product manufacturer only, while the COA of drug substance manufacturer is not submitted.
Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug substance and drug product.	Firm has submitted COA of working standard from drug substance manufacturer which has been standardized against USP reference standard. However drug product manufacturer is using working standard of meropenem Batch No. SI/MPM/00060120 manufactured by M/s Sterile India.
Justify the master formulation containing 1140mg of meropenem trihydrate for manufacturing of 1g meropenem for injection, since the drug substance contains meropenem blended with 15.10 to 16.50% w/w of sodium carbonate.	Firm has submitted calculation to justify the filled weight. As per calculations submitted by the firm the weight 1140mg per vial is calculated on theoretical basis considering that the drug substance has 100% assay, while the actual dispensing is to be made on the basis of actual % assay of the meropenem.
Justify the use of 5% overage in the formulation, since the justification submitted in this regard is not supported by any guidelines.	We hereby justify that in development stage we added 5% extra meropenem sterile powder for injection in initial batches. After completion of stability study degradation is no more than 2 – 3% within the limit assay range is 90 – 120% so no more 5% meropenem sterile powder for injection is added.
Submit results of compatibility studies in section 3.2.P.2.6.	Firm has submitted result of compatibility studies of the drug product with WFI.
Justify how the time and temperature of sterilization cycle is directly selected without any protocols for its validation.	Firm has submitted summary report of autoclave machine re qualification instead of providing justification.
Provide detailed method of sample stock solution preparation instead of mentioning the general statement "Constitute a container of Meropenem for Injection with a volume of water, corresponding to the quantity of solvent specified in the labelling".	Firm has not submitted complete method of analysis of the drug product in which the method of sample solution preparation is explained.

Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	Firm has submitted that we are using potency of working standard as percentage. USP taking the potency in mg/mg which is converted into percentage by multiplying this ratio with 100. Firm has submitted calculation to justify that their formula is equivalent to USP. However, the USP formula used by the firm is different from that specified in USP.
Analytical method verification studies have not been conducted and evaluated in the light of USP general chapters and ICH guidelines.	Firm has submitted verification studies of the analytical method dated 21-01-2021, while the analytical method of the drug product was revised and updated on 12-07-2021.
Justify why the drug product specifications does not contain the test for sodium contents as recommended by USP.	In Meropenem trihydrate injection label claim is as meropenem while trihydrate and sodium considered as impurity. We are verifying the meropenem by HPLC and due to unavailability of the atomic absorption we were verifying the sodium content by titration method. Moreover, for verification purpose, we analysed sodium content from PCSI and Citi Pharma with atomic absorption. And now we have atomic absorption in our facility and we have changed our SOP accordingly and now we are conducting each and every analysis of sodium content in our facility as per USP monograph.
Justify the test of accuracy in analytical method validation without specifying the concentrations of the solution which are analysed for accuracy. Further justify the use of solutions having low, medium, and high concentration of sample without specifying their exact concentration. Such words are not recommended by any scientific guidelines.	Firm has submitted that we had performed the accuracy by making a concentration of standard preparation and three concentrations. The concentrations used by the firm for accuracy test is 0.16mg/ml, 0.20mg/ml and 0.24mg/ml. As per the analytical method the standard solution concentration is 0.11mg/ml and the concentration used by the firm to study accuracy does not include the said concentration.
Linearity and range have been studied from 70% to 120% of the solution wherein the area under curve for 100% solution was 4691449 while in accuracy studies in the same method none of the solution (either low, medium or high concentration) achieved such area although the concentration of the solution is expected to be the same. Justification is required in this regard.	Two different samples were prepared for linearity and accuracy parameter of analytical method verification, for linearity parameter from the first dilution 6 further second dilutions 70%, 80%, 90%, 100%, 110% and 120% were prepared while in accuracy 3 further second dilutions low, medium and high were prepared. Because the weights of the sample are different in linearity and accuracy parameters that's why the area achieved is different for both parameters.
In linearity studies the area under curve for 100% solution was 4691449, while in stability studies the area under curve of the sample solution having exactly same concentration is reported to be 11769485. Justification is required in this regard how such huge difference in area under the curve can exist in the analysis and how this method can be considered reliable and verified.	In linearity the sample solution preparation is different from the sample preparation of finished product. In linearity a concentration of standard taken to prepare first dilution then make second dilution by taking 7ml, 8ml, 9ml, 10ml, 11ml, 12ml from the first dilution, second dilution of 10ml is considered as 100% concentration while in finished good the dilution contain 100mg of sample that's why area under curve for 100% solution is different from the area of 100mg in finished product.
The analytical method verification studies have been conducted in January 2021 while the batches were manufactured in 2017. Justification is required in this regard.	In 2017, we had completed analytical method verification by performing three parameters which are linearity, system suitability and specificity while when we submit the CTD dossier we came to know the DRAP requirement of accuracy and repeatability, then we had complete the analytical method verification by performing five parameters which are linearity, system suitability, specificity accuracy and repeatability.
Justify the limit of sodium content in the in house generated COA of drug substance, in which limit of sodium content is taken as 6.0% to 9.3% and the drug substance was passed on the basis of results of 9.12%, while the drug substance manufacturer specifies the limit of sodium content as 6.56% to 7.20%.	In past we were doing sodium content analysis by titration method (due to unavailability of AAS) the result was 9.12% limit of sodium content is 6.0% - 9.3% while the drug substance manufacturer specifies the sodium content as 6.65 to 7.20%. Now we are doing sodium content with AAS according to USP.

As per the submitted results of sodium content in meropenem injection by CITI Pharma, the results of % sodium content is 7.867%, while USP specifies the acceptance criteria to be 80%–120% of the labeled amount of sodium. Justify how your results complies USP specifications keeping in view the labelled amount of sodium in your product.	Firm has not submitted any justification
Justify the use of commercial lot of meropenem for injection (batch number SI/MPM/00060120) manufactured by sterile India as working standard since USP recommends that reference standard should be pure meropenem trihydrate.	The assay of meropenem trihydrate USP reference standard lot# J0K434, is 87.3% meropenem. Similarly, by comparing with reference standard we prepare our meropenem trihydrate working standard in which 82.12% is meropenem present. Actually the material used in USP Reference standard and the working standard is the same as meropenem trihydrate because the product label claim is meropenem, therefore we have to calculate the assay against the purity of material as meropenem which is 87.3% in USP Reference standard and 82.12% in working standard.
Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm has not submitted details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Further documents confirming import of these relevant batches are also required.
Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point, since the submitted chromatograms and analytical reports are without any proper sequence.	Firm has not yet submitted stability study data in proper sequence with COA for each time point, raw data sheets and chromatograms. Raw data sheets are not submitted. Further the calculation formula used for the calculation of assay result is also different from USP as well as the method of sample and standard solution preparation.
Provide Reference of previous approval of applications with stability study data of the firm (if any)	No response submitted by the firm
Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.	No response submitted by the firm
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	No response submitted by the firm

Decision of 316th meeting of Registration Board:

Deferred for following:

- Submission of differential fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.
- Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.
- Scientific justification for use of 5% overage in the formulation.
- Submission of complete protocols of process validation studies of the drug product.
- Submission of detailed method of analysis of the drug product with details of sample solution preparation.
- Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.
- Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.
- Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm

1.	Submission of differential fee as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has submitted differential fee 5,000/- vide slip number 658476562996 dated 20-05-2022.
2.	Submission of COA of relevant batch of drug substance from drug substance manufacturer used in the manufacturing of batches for which stability study data is submitted.	Firm has submitted COA of relevant batch of drug substance generated by drug substance manufacturer.
3.	Scientific justification for using commercial batch manufactured by M/s Sterile India as working standard.	This firm has submitted that the assay of Meropenem Trihydrate USP reference standard lot # J0k434 is 87.3%. Therefore, we used sterile India material as working Standard having potency 82.02% by using standardization procedure with USP reference standard. Material used for batch manufacturing is from Aurobindo China and working standard prepared is of Sterile India having Potency 82.02% COA's for Reference standard & working standard along with standardization procedure is submitted by the firm.
4.	Scientific justification for use of 5% overage in the formulation.	Firm has submitted that an overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
5.	Submission of complete protocols of process validation studies of the drug product.	Firm has submitted general protocols for process validation. **Firm has not submitted specific protocols for the process validation of applied product.**
6.	Submission of detailed method of analysis of the drug product with details of sample solution preparation.	Firm has submitted detailed method of analysis of the drug product, **However in the submitted method, sample solution preparation method is still not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions.** Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
7.	Scientific justification for using calculation formula for assay testing which is different from that specified in USP monograph.	Firm has submitted that they are using the potency of working standard as percentage. USP taking the Potency into mg/mg which is covered into percentage multiplying the ratio with 100 so there is no difference between the USP formula & our standard operating formula further more we have amended our SOP with respect to the formula given in USP. **However, the newly used calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard. The new formula is also not exactly as per USP monograph.**
8.	Revision of drug product specifications in the light of USP monograph and inclusion of test for sodium content along with submission of fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per	Firm has now added sodium content test in their specifications. Firm has also submitted fee 7,500/- vide slip number 45752149528 dated 20-05-2022. **However, no data regarding the sodium content testing during stability studies is provided.**

	notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
9.	Scientific justification for the analytical method verification studies of the drug product which is not performed as per ICH guidelines.	Firm has not justified the previous validation reports, instead the firm has submitted new report in which the analysis is carried out on July 2022. The new report was performed in line with ICH recommendations.
10.	Submission of stability study data of three commercial batches in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.	Firm has submitted data in section 3.2.P.8.3. The evaluation os submitted data is as under:

Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 3298/E1/2019) issued by Drugs Control Administration, Government of Telangana dated 11-02-2020. The certificate is valid till 3 years from the date of issue.
Documents for the procurement of API with approval from DRAP (in case of import).	**1705205135, 1705205096:** Firm has submitted copy of commercial invoice cleared dated 19-10-2017 specifying import of 20Kg meropenem for lot number 1705205135, 1705205096. The invoice is cleared by AD (I&E) DRAP. **1705203623:** Firm has submitted copy of commercial invoice cleared dated 12-09-2017 specifying import of 15Kg meropenem for lot number 1705203623. The invoice is cleared by AD (I&E) DRAP.
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record of product testing including HPLC chromatogram and raw data sheets
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for stability chambers for accelerated and real time stability study.

Decision of 320th meeting of Registration Board:

Deferred for following:

- Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.
- Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.
- Submission of specific protocols for the process validation of applied product.
- Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.
- Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm

1.	Clarification for use of 5% overage in sterile products and specifications of the manufactured products in the light of approved specifications and pharmacopoeial monographs.	An overage is used to cover losses during manufacturing. Initially we used extra 5% of Meropenem to deliver our product with exact quantity of API in injection, the idea behind was to deliver exact quantity of the active substance. After that our product was stable throughout its shelf life so no need to add extra 5% overage. In general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Overages are nothing but the extra quantity of material taken, which is lost during process stage.ICH Q8 guide line, provide a structured way to define product critical quality attributes. We are not using any overage in the manufacturing of Meropenem injection
2.	Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.	Capacity assessment report is not yet received.
3.	Submission of specific protocols for the process validation of applied product.	Firm has submitted process validation protocols
4.	Submission of preparation sample solution is required since it is not clear in terms of exact volume of water used to reconstitute the contents of vial and then how to make further dilutions. Furthermore, the calculation formula use weight of sample and standard while USP recommends to use concentration of sample and standard.	Firm has submitted revised testing method and specifications dated 30-09-2022. The revised method is again unclear about the sample solution preparation method since it is not clear in terms of exact volume of water used to reconstitute the contents of vial.
5.	Clarification regarding use of formula which is different from the formula as recommended by USP for calculation of assay.	Firm has submitted revised testing method and specifications dated 30-09-2022. The formula used for calculation of assay of drug product is different from USP since USP recommends concentration of sample and standard solution while the firm is using weight of sample and standard solution. Firm has again submitted another revised testing method and specifications dated 23-11-2022 in which the testing method is as per USP monograph along with test for sodium contents.

Proceedings & Decision: Registration Board was apprised that the applied formulation has already been approved in 312th meeting opf Registration Board for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, wherein following submission had also been made by the firm and above mentioned points have been addressed and responded:

1. **Evidence for purchase of atomic absorption spectrophotometer in the form of purchase order dated 14-06-2021, deliver challan dated 19-06-2021 & invoice No. 06/3029 dated 18-06-2021.**
2. **Installation and operational qualification reports of atomic absorption spectrophotometer**
3. **Analysis report of Sodium Content in Mopen (Meropenem) Injection by M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**

On basis of above cited reference Registration Board decided to approve instant application. Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.

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

- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**

Case No. 03 Export facilitation cases

Case No. 1: M/s Herbion Pakistan Pvt Ltd. Industrial Triangle, Kahuta Road, Islamabad

Assistant Director PR-I / EFD vide its letter No. F.1-6/2019-PR-I (EFD) dated 6th October 2022 informed that as per decision of 133rd meeting of DRAP Authority wherein it was decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicine (to a maximum of 15 such molecules) during a financial year.

In compliance to the above decision M/s Herbion Pakistan Pvt Ltd. Islamabad have achieved benchmark of more than 100,000 USD and submitted their applications for priority consideration including following applications:

- Diance-Met 12.5/500mg Tablet
- Diance-Met 12.5/1000mg Tablet
- Diance-Met 5/1000mg Tablet

749.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan Pvt Ltd. Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate dated 17-07-2019. The certificate is valid till 20-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of revised / relocated section letter dated 09-04-2020 in which Tablet (general) section is specified.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24971: 25-11-2019
	Details of fee submitted	PKR 20,000/-: 25-11-2019
	The proposed proprietary name / brand name	**DIANCE-MET 5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…5mg Metformin HCl…1000mg
	Pharmaceutical form of applied drug	Beige yellow oblong shaped plain on both sides
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	14's (2x7's)
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xelglu-Met Tablet by Hilton
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. **Metformin:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.39615
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Metformin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Xenglu-Met Tablet of Hilton Pharma.

		Firm has submitted results of CDP for their product against Xenglu-Met Tablet of Hilton Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. **Metformin:** Aarti Drugs Limited Plot No. 211-213, Road No.2G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.		
API Lot No.	**Empagliflozin:** H-E-20201125-D03-E06-01 **Metformin:** 10010279		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DIAM(5/1000)-ST-001	DIAM(5/1000)-ST-002	DIAM(5/1000)-ST-003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	22-10-2021	22-10-2021	22-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their previous onsite inspection for Vocab 10 and 20mg tablet which was conducted on 15-11-2021 and was considered by the Board in its 313rd meeting. The report cofirms following points: • FPP testing had been conducted on HP-QCE-048 (shimadzu LC-2030) and HP-QCE-001 (shimadzu 2080), which were 21 CFR compliant. • The audit trail report was reproduced at the time of inspection. • Adequate monitoring and control were available for stability chamber.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of DML certificate No. Liao20150233, dated: 21/12/2017 valid till 20/12/2022, issued by Food & Drug Administration of Liaoning Province- China is submitted. **Metformin:** Copy of GMP Certificate (No. 20031933) for M/s Aarti Drugs Limited issued by Food and Drug Control Administration, Gujrat State India is submitted. It is valid till 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has also submitted copy of commercial invoice specifying import of 0.38Kg Empagliflozin. The invoice is cleared by AD (I&E) DRAP dated 20-04-2021.

		Metformin: Firm has also submitted copy of commercial invoice specifying import of 25Kg Metformin HCl. The invoice is cleared by AD (I&E) DRAP dated 07-10-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC(III)::

The application was initially submitted on 25-11-2019 without product development and stability study data. The firm was issued a letter of shortcoming dated 26-12-2019. Later the firm submitted complete data on 18th April 2022 and the data was evaluated and following further shortcomings were communicated to the firm. The response of the firm is tabulated below:

Shortcomings communicated	**Response by the firm**
Submit drug substance specifications and analytical method from drug product manufacturer for metformin hydrochloride.	The firm has submitted specifictations and analytical method of metformin hydrochloride from Herbion Pharma.
Submit verification studies of analytical method of metformin hydrochloride drug substance.	Firm has submitted verification studies of the analytical method of metformin hydrochloride drug substance.
Submit stability study data of metformin hydrochloride drug substance as per zone IV-A conditions.	Firm has submitted metformin hydrochloride drug substance stability study data as per zone IV-A conditions.
Submit GMP certificate for API manufacturer of metformin hydrochloride.	Copy of GMP Certificate (No. 20031933) for M/s Aarti Drugs Limited issued by Food and Drug Control Administration, Gujrat State India is submitted. It is valid till 19-03-2023.
Clarify the exact source of empaglifloin drug substance, since Beijing Huikang Pharmaceuticals is mentioned in module 1 and 3.	Firm has submitted that Beijing Huikang is the DMF holder / supplier for this drug substance while it is manufactured at Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. The commercial invoice and clearance certificate issued by AD (I&E) also specify that the manufacturer is Fuxin Long Rui Pharmaceutical.
Submit copy of BMR of three stability batches	Firm has submitted copy of BMR of the three batches

Decision of 317th meeting of Registration Board:

Deferred for consideration on its turn since the product development and stability study data was submitted in April 2022.

Submission by the firm:

Firm has requested to consider their application of priority basis as per export facilitation as per the letter of Assistant Director PR-I / EFD (letter No. F.1-6/2019-PR-I (EFD) dated 6th October 2022) wherein it was informed that M/s Herbion Pakistan Pvt Ltd. Islamabad have achieved benchmark of more than 100,000 USD and submitted their applications for priority consideration as per decision of 133rd meeting of DRAP Authority wherein it was decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicine (to a maximum of 15 such molecules) during a financial year.

The application was already evaluated and presented by the Board and was deferred for consideration on its turn since the product development and stability study data was submitted in April 2022.

Decision: Approved.

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
750.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan Pvt Ltd. Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate dated 17-07-2019. The certificate is valid till 20-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of revised / relocated section letter dated 09-04-2020 in which Tablet (general) section is specified.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24968: 25-11-2019
	Details of fee submitted	PKR 20,000/-: 25-11-2019
	The proposed proprietary name / brand name	**DIANCE-MET 12.5/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…12.5mg Metformin HCl…500mg
	Pharmaceutical form of applied drug	White colored, oblong shaped break line on one side and other side is plain.
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	14's (2x7's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xelglu-Met Tablet by Hilton
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. **Metformin:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.39615
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months. **Metformin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Xenglu-Met Tablet of Hilton Pharma. Firm has submitted results of CDP for their product against Xenglu-Met Tablet of Hilton Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. **Metformin:** Aarti Drugs Limited Plot No. 211-213, Road No.2G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.
API Lot No.	**Empagliflozin:** H-E-20201125-D03-E06-01 **Metformin:** 10010279
Description of Pack (Container closure system)	Alu-alu blister pack
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DIAM(12.5/500)-ST-001	DIAM(12.5/500)-ST-002	DIAM(12.5/500)-ST-003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	22-10-2021	22-10-2021	22-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their previous onsite inspection for Vocab 10 and 20mg tablet which was conducted on 15-11-2021 and was considered by the Board in its 313rd meeting. The report cofirms following points: • FPP testing had been conducted on HP-QCE-048 (shimadzu LC-2030) and HP-QCE-001 (shimadzu 2080), which were 21 CFR compliant. • The audit trail report was reproduced at the time of inspection. • Adequate monitoring and control were available for stability chamber.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of DML certificate No. Liao20150233, dated: 21/12/2017 valid till 20/12/2022, issued by Food & Drug Administration of Liaoning Province- China is submitted. **Metformin:** Copy of GMP Certificate (No. 20031933) for M/s Aarti Drugs Limited issued by Food and Drug Control Administration, Gujrat State India is submitted. It is valid till 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has also submitted copy of commercial invoice specifying import of 0.38Kg Empagliflozin. The invoice is cleared by AD (I&E) DRAP dated 20-04-2021. **Metformin:** Firm has also submitted copy of commercial invoice specifying import of 25Kg Metformin HCl. The invoice is cleared by AD (I&E) DRAP dated 07-10-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC(III)::

The application was initially submitted on 25-11-2019 without product development and stability study data. The firm was issued a letter of shortcoming dated 26-12-2019. Later the firm submitted complete data in 18th

April 2022 and the data was evaluated and following further shortcomings were communicated to the firm. The response of the firm is tabulated below:

Shortcomings communicated	**Response by the firm**
Submit drug substance specifications and analytical method from drug product manufacturer for metformin hydrochloride.	The firm has submitted specifictations and analytical method of metformin hydrochloride from Herbion Pharma.
Submit verification studies of analytical method of metformin hydrochloride drug substance.	Firm has submitted verification studies of the analytical method of metformin hydrochloride drug substance.
Submit stability study data of metformin hydrochloride drug substance as per zone IV-A conditions.	Firm has submitted metformin hydrochloride drug substance stability study data as per zone IV-A conditions.
Submit GMP certificate for API manufacturer of metformin hydrochloride.	Copy of GMP Certificate (No. 20031933) for M/s Aarti Drugs Limited issued by Food and Drug Control Administration, Gujrat State India is submitted. It is valid till 19-03-2023.
Clarify the exact source of empaglifloin drug substance, since Beijing Huikang Pharmaceuticals is mentioned in module 1 and 3.	Firm has submitted that Beijing Huikang is the DMF holder / supplier for this drug substance while it is manufactured at Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. The commercial invoice and clearance certificate issued by AD (I&E) also specify that the manufacturer is Fuxin Long Rui Pharmaceutical.
Submit copy of BMR of three stability batches	Firm has submitted copy of BMR of the three batches

Decision of 317th meeting of Registration Board:
Deferred for consideration on its turn since the product development and stability study data was submitted in April 2022.

Submission by the firm:
Firm has requested to consider their application of priority basis as per export facilitation as per the letter of Assistant Director PR-I / EFD (letter No. F.1-6/2019-PR-I (EFD) dated 6th October 2022) wherein it was informed that M/s Herbion Pakistan Pvt Ltd. Islamabad have achieved benchmark of more than 100,000 USD and submitted their applications for priority consideration as per decision of 133rd meeting of DRAP Authority wherein it was decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicine (to a maximum of 15 such molecules) during a financial year.
The application was already evaluated and presented by the Board and was deferred for consideration on its turn since the product development and stability study data was submitted in April 2022.

Decision: Approved.

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

751.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan Pvt Ltd. Industrial Triangle, Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of GMP certificate dated 17-07-2019. The certificate is valid till 20-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of revised / relocated section letter dated 09-04-2020 in which Tablet (general) section is specified.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24976: 25-11-2019
	Details of fee submitted	PKR 20,000/-: 25-11-2019
	The proposed proprietary name / brand name	**DIANCE-MET 12.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…12.5mg Metformin HCl…1000mg
	Pharmaceutical form of applied drug	Oblong shaped, blue colored film coated tablets, plain on both sides
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	14's (2x7's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xelglu-Met Tablet by Hilton
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. **Metformin:** Aarti Drugs Limited Plot No. 211 - 213, Road No.2G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.39615
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.

		Metformin: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Xenglu-Met Tablet of Hilton Pharma. Firm has submitted results of CDP for their product against Xenglu-Met Tablet of Hilton Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China. **Metformin:** Aarti Drugs Limited Plot No. 211-213, Road No.2G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.		
API Lot No.	**Empagliflozin:** H-E-20201125-D03-E06-01 **Metformin:** 10010279		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DIAM(12.5/1000)-ST-001	DIAM(12.5/1000)-ST-002	DIAM(12.5/1000)-ST-003
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	22-10-2021	22-10-2021	22-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their previous onsite inspection for Vocab 10 and 20mg tablet which was conducted on 15-11-2021 and was considered by the Board in

		its 313rd meeting. The report cofirms following points: • FPP testing had been conducted on HP-QCE-048 (shimadzu LC-2030) and HP-QCE-001 (shimadzu 2080), which were 21 CFR compliant. • The audit trail report was reproduced at the time of inspection. • Adequate monitoring and control were available for stability chamber.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of DML certificate No. Liao20150233, dated: 21/12/2017 valid till 20/12/2022, issued by Food & Drug Administration of Liaoning Province- China is submitted. **Metformin:** Copy of GMP Certificate (No. 20031933) for M/s Aarti Drugs Limited issued by Food and Drug Control Administration, Gujrat State India is submitted. It is valid till 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has also submitted copy of commercial invoice specifying import of 0.38Kg Empagliflozin. The invoice is cleared by AD (I&E) DRAP dated 20-04-2021. **Metformin:** Firm has also submitted copy of commercial invoice specifying import of 25Kg Metformin HCl. The invoice is cleared by AD (I&E) DRAP dated 07-10-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted HPLC audit trail reports and 21 CFR compliance certificate
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC(III)::

The application was initially submitted on 25-11-2019 without product development and stability study data. The firm was issued a letter of shortcoming dated 26-12-2019. Later the firm submitted complete data in 18th April 2022 and the data was evaluated and following further shortcomings were communicated to the firm. The response of the firm is tabulated below:

Shortcomings communicated	**Response by the firm**
Submit drug substance specifications and analytical method from drug product manufacturer for metformin hydrochloride.	The firm has submitted specifictations and analytical method of metformin hydrochloride from Herbion Pharma.
Submit verification studies of analytical method of metformin hydrochloride drug substance.	Firm has submitted verification studies of the analytical method of metformin hydrochloride drug substance.
Submit stability study data of metformin hydrochloride drug substance as per zone IV-A conditions.	Firm has submitted metformin hydrochloride drug substance stability study data as per zone IV-A conditions.
Submit GMP certificate for API manufacturer of metformin hydrochloride.	Copy of GMP Certificate (No. 20031933) for M/s Aarti Drugs Limited issued by Food and Drug Control Administration, Gujrat State India is submitted. It is valid till 19-03-2023.
Clarify the exact source of empaglifloin drug substance, since Beijing Huikang Pharmaceuticals is mentioned in module 1 and 3.	Firm has submitted that Beijing Huikang is the DMF holder / supplier for this drug substance while it is manufactured at Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City

	Liaoning Province China. The commercial invoice and clearance certificate issued by AD (I&E) also specify that the manufacturer is Fuxin Long Rui Pharmaceutical.
Submit copy of BMR of three stability batches	Firm has submitted copy of BMR of the three batches

Decision of 317th meeting of Registration Board:
Deferred for consideration on its turn since the product development and stability study data was submitted in April 2022.

Submission by the firm:
Firm has requested to consider their application of priority basis as per export facilitation as per the letter of Assistant Director PR-I / EFD (letter No. F.1-6/2019-PR-I (EFD) dated 6th October 2022) wherein it was informed that M/s Herbion Pakistan Pvt Ltd. Islamabad have achieved benchmark of more than 100,000 USD and submitted their applications for priority consideration as per decision of 133rd meeting of DRAP Authority wherein it was decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicine (to a maximum of 15 such molecules) during a financial year.
The application was already evaluated and presented by the Board and was deferred for consideration on its turn since the product development and stability study data was submitted in April 2022.

Decision: Approved.

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

Case No. 2: M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi
Assistant Director PR-I / EFD vide its letter No. F.1-6/2019-PR-I (EFD) dated 6th October 2022 informed that as per decision of 133rd meeting of DRAP Authority wherein it was decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicine (to a maximum of 15 such molecules) during a financial year.
In compliance to the above decision M/s Swiss Pharmaceuticals Pvt Ltd., Karachi have achieved benchmark of more than 100,000 USD and submitted their applications for priority consideration including following applications:

752.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Swistat 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate…10mg
	Diary No. Date of R& I & fee	Dy No. 16859: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lipiget Tablet by Getz
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
753.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Swistat 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate…20mg

	Diary No. Date of R& I & fee	Dy No. 16860: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lipiget Tablet by Getz
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
754.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Swistat 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as calcium trihydrate…40mg
	Diary No. Date of R& I & fee	Dy No. 16861: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lipiget Tablet by Getz
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
755.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Zine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cetirizine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16849: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Baydal Tablet by Bayer
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
756.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Zine 5mg Syrup
	Composition	Each 5ml Contains: Cetirizine HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 16848: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Piperazine derivatives

	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Baydal Syrup by Bayer
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
757.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Swicar 50mg/ml Injection
	Composition	Each ml Contains: Iron As Ferric Carboxymaltose…50mg
	Diary No. Date of R& I & fee	Dy No. 16846: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	10ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Bio-Maltose Injection by Bio-Lab
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
758.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Asmide 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Dy No. 16857: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
759.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Asmide 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R& I & fee	Dy No. 16858: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
760.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Asmide 10mg/ml Injection
	Composition	Each ml Contains: Lacosamide…10mg
	Diary No. Date of R& I & fee	Dy No. 16856: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	20ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lacolep Injection by Hilton
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
761.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Telmi 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R& I & fee	Dy No. 16862: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
762.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Telmi 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy No. 16863: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton

	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
763.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Telmi 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy No. 16864: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Telsan Tablet by Hilton
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
764.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Telmi-H 40/12.5 mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy No. 16865: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Co-Telsan Tablet by Hilton
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	

Case No. 04 Registration applications of locally manufactured products applied on Form 5

a. New cases in which firm has submitted replies

765	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**

	Brand Name +Dosage Form + Strength	Mapez 0.5mg Tablet
	Composition	Each Tablet Contains: Clonazepam…0.5mg
	Diary No. Date of R& I & fee	Dy No. 16480: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Rivotril Tablet by Martin Dow
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Firm has Tablet (psychotropic) section.
	Decision: Approved.	
766	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Mapez Tablet 2mg
	Composition	Each Tablet Contains: Clonazepam…2mg
	Diary No. Date of R& I & fee	Dy No. 16481: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Rivotril Tablet by Martin Dow
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Firm has Tablet (psychotropic) section.
	Decision: Approved.	
767	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Plitox Tablet 2.5/0.25mg
	Composition	Each Tablet Contains: Diphenoxylate HCl…2.5mg Atropine Sulphate…0.25mg
	Diary No. Date of R& I & fee	Dy No. 16487: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipropulsives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lomotil Tablet by Searle
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Diphenoxylate HCl…2.5mg Atropine Sulphate…0.025mg
	Decision: Deferred for revision of formulation as per the Innovator's product along with submission of fee 30,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
768	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**

	Brand Name +Dosage Form + Strength	Plioxicam 15mg tablet
	Composition	Each Tablet Contains: Meloxicam…15mg
	Diary No. Date of R& I & fee	Dy No. 16479: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Melor Tablet by Sami
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
769	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Methadate Tablet 10mg
	Composition	Each Tablet Contains: Methylphenidate HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16486: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Centrally acting sympathomimetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ritalin Tablet by Novartis
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Firm has Tablet (psychotropic) section.
	Decision: Approved.	
770	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Metazole Tablet 400mg
	Composition	Each Tablet Contains: Metronidazole…400mg
	Diary No. Date of R& I & fee	Dy No. 16478: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Flagyl Tablet by Sanofi Aventis
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Reference product is available as film coated tablet while you have applied for uncoated tablet. Revise your formulation as per the reference product along with submission of 7,500/- fee.
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Metronidazole…400mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
771	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Plaflox 400mg Tablet

	Composition	Each Tablet Contains: Moxifloxacin As HCl…400mg
	Diary No. Date of R& I & fee	Dy No. 16483: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Avelox Tablet by Bayer
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Reference product is available as film coated tablet while you have applied for uncoated tablet. Revise your formulation as per the reference product along with submission of 7,500/- fee.
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Moxifloxacin as HCl…400mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
772	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd** **Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Temaz 15mg Capsule
	Composition	Each Capsule Contains: Temazepam…15mg
	Diary No. Date of R& I & fee	Dy No. 16484: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Restoril Capsule USFDA Approved.
	Me-too status	Restoril Capsule by Novartis
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Evidence of approval of requisite manufacturing facility / section approval from Licensing Division DRAP.
	Decision: Registration Board rejected the application since firm does not have approval for required manufacturing facility / section i.e., "Capsule (Psychotropic) section" from CLB.	
773	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Temaz Capsule 30mg
	Composition	Each Capsule Contains: Temazepam…30mg
	Diary No. Date of R& I & fee	Dy No. 16485: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Restoril Capsule USFDA Approved.
	Me-too status	Restoril Capsule by Novartis
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Evidence of approval of requisite manufacturing facility / section approval from Licensing Division DRAP.
	Decision: Registration Board rejected the application since firm does not have approval for required manufacturing facility / section i.e., "Capsule (Psychotropic) section" from CLB.	

774	**Name and address of manufacturer / Applicant**	**M/s Pliva Pakistan Pvt Ltd** **Plot # B-77, Hub Industrial Trading Estate, Baluchistan**
	Brand Name +Dosage Form + Strength	Polfi 10mg Tablet
	Composition	Each Tablet Contains: Zolpidem Tartrate…10mg
	Diary No. Date of R& I & fee	Dy No. 16482: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Benzodiazepine related drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Stilnox Tablet by Sanofi Aventis
	GMP status	Last inspection report dated 15-02-2022 concludes that the overall GMP of the firm is rated as good.
	Remarks of the Evaluator[3].	• Firm has Tablet (psychotropic) section. • Reference product is available as film coated tablet while you have applied for uncoated tablet. Revise your formulation as per the reference product along with submission of 7,500/- fee.
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Zolpidem Tartrate…10mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
775	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals** **Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Betagen Cream 0.5mg/1mg
	Composition	Each gram of cream contains: Betamethasone…0.5mg Gentamicin…1mg
	Diary No. Date of R& I & fee	Dy No. 14443: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids, Combinations With Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications (JP Monograph for Betamethasone Valerate and Gentamicin Sulfate Cream)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Mibetin 1 mg/g + 0.5 mg/g Cream (gentamicin sulfate, betamethasone dipropionate).
	Me-too status	
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Latest GMP inspection report conducted within a period of last three years.	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
2.	Reference of finished product specifications.	Firm has submitted USP monograph of API and betamethasone cream and gentamicin ointment separately, **however for the applied product no reference has been submitted.**
3.	Clarify the salt form of betamethasone as well as gentamicin, since both	Firm has submitted revised label claim in which salt form has been clarified. The revised label claim is as follows:

	betamethasone dipropionate and betamethasone valerate are available.	Each gram of cream contains: Betamethasone (as dipropionate)…0.5mg Gentamicin (as sulphate)……1mg **Firm has NOT submitted any fee for correction of salt form.**
4.	Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP.	Firm has submitted letter of issuance of DML dated 24-08-2016 specifying Tablet (General), Capsule (General), Topical (General), Sachet (General), Liquid Syrup (General) and Oral dry powder for suspension (General) section.
5.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	Effigenta Cream by Mass Pharma (Reg # 024735)

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

Each gram of cream contains:
Betamethasone (as dipropionate)…0.5mg
Gentamicin (as sulphate)……1mg

- **Firm shall submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**

77(**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals** **Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
Brand Name +Dosage Form + Strength	Moncep 125mg/5ml Dry Suspension
Composition	Each 5ml Contains: Ciprofloxacin as Hcl…250mg
Diary No. Date of R& I & fee	Dy No. 14436: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Fluoroquinolones
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Registration Board in 269th meeting approved the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension
Me-too status	Novidat suspension by Sami
GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Latest GMP inspection report conducted within a period of last three years.	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
2.	Reference of finished product specifications.	Firm has submitted USP specifications.
3.	The applied brand name is Moncep 125mg/5ml Dry Suspension while the label claim specifies Ciprofloxacin as HCl 250mg. Clarification is required in this regard.	Firm has submitted that the applied formulation contains 125mg and the correct label claim is as under: Each 5ml Contains: Ciprofloxacin..…125mg Firm has revised the salt form from Ciprofloxacin HCl to base. **Firm has not submitted fee for this revision.**
4.	The innovator's product is supplied with a diluent while your product does not depict the use of any diluent. Clarification is required in this regard..	**No response submitted against this query.**

5.	Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP.	Firm has submitted letter of issuance of DML dated 24-08-2016 specifying Tablet (General), Capsule (General), Topical (General), Sachet (General), Liquid Syrup (General) and Oral dry powder for suspension (General) section.

Decision: Approved with following label claim:

Each 5ml Contains:

Ciprofloxacin.….125mg

- **Firm shall submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**
- **Firm shall market the product along with diluent as per the innovator's product as per the decision of 290th and 313th meeting of Registration Board.**

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Name and address of manufacturer / Applicant	**M/s Moon Pharmaceuticals** **Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
Brand Name +Dosage Form + Strength	Moncep 250mg/5ml Dry Suspension
Composition	Each 5ml Contains: Ciprofloxacin …250mg
Diary No. Date of R& I & fee	Dy No. 14437: 07-03-2019 PKR 20,000/-: 07-03-2019
Pharmacological Group	Fluoroquinolones
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	MHRA Approved
Me-too status	Novidat suspension by Sami
GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Latest GMP inspection report conducted within a period of last three years.	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
2.	Reference of finished product specifications.	Firm has submitted USP specifications.
3.	Innovator's product contains ciprofloxacin base while you have applied for HCl salt of ciprofloxacin. Revise your formulation along with submission of full fee of registration.	Firm has revised the salt form from Ciprofloxacin HCl to base. **Firm has not submitted fee for this revision.**
4.	The innovator's product is supplied with a diluent while your product does not depict the use of any diluent. Clarification is required in this regard..	**No response submitted against this query.**
5.	Evidence of requisite manufacturing facility / section approval letter from Licensing Division DRAP.	Firm has submitted letter of issuance of DML dated 24-08-2016 specifying Tablet (General), Capsule (General), Topical (General), Sachet (General), Liquid Syrup (General) and Oral dry powder for suspension (General) section.

Decision: Approved

- **Firm shall submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**

	• **Firm shall market the product along with diluent as per the innovator's product as per the decision of 290th and 313th meeting of Registration Board.**	
778	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Difen K 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac Potassium…50mg
	Diary No. Date of R& I & fee	Dy No. 14454: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Diclorep Tablet by Sami
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
779	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Isotret E Gel 0.5/20mg
	Composition	Each gram of gel contains: Isotretinoin…0.5mg Erythromycin…20mg
	Diary No. Date of R& I & fee	Dy No. 14442: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Oratraxin gel by Crystolite
	GMP status	
	Remarks of the Evaluator[3].	

Sr. No	Observation	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	**Firm has not submitted any response**

	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
780	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Monitra 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole (as IR pellets)…100mg
	Diary No. Date of R& I & fee	Dy No. 14449: 07-03-2019

		PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antimycotics For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Icon Capsule by Ferozesons
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
781	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Monlet 125mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy No. 14453: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Aromatase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Femara Tablet by Novartis
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	

Sr. No	Observation	Response by the firm
1.	The brand name and covering letter specifies Monlet 125mg Tablet while in label claim firm have mentioned Letrozole 2.5mg.	**Firm has submitted that it was a typo mistake.**

	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
782	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Lormex 8mg Tablet
	Composition	Each Film coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy No. 14452: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
	Me-too status	Zafon Tablets by Getz
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	

Sr. No	Observation	Response by the firm
1.	Revise your label claim to film coated tablet as per the reference product along with submission of 7,500/- fee.	Firm has revised the label claim to film coated tablet how firm has **not** submitted fee.

Decision: Approved with Innovator's specifications. Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.

783	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals** **Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Monpro 20mg Sachet
	Composition	Each Sachet Contains: Omeprazole…20mg Sodium bicarbonate……1680mg
	Diary No. Date of R& I & fee	Dy No. 14439: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA
	Me-too status	Risek Insta Sachet by Getz
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
784	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals** **Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Monpro Max Sachet 40/1680mg
	Composition	Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg
	Diary No. Date of R& I & fee	Dy No. 14440: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA
	Me-too status	Risek Insta Sachet by Getz
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
785	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Monlin 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy No. 14445: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anticonvulsant
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Gabica Capsule by Getz
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	• Firm has initially claimed in house specifications while the product monograph is available in latest edition of BP monograph. Firm has now revise the specifications to BP along with submission of 7,500/- fee.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
786	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Metsita 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 14451: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved

	Me-too status	Treivamet Tablet by Getz
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years alongwith Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
787	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Martilate sachet 2g
	Composition	Each Sachet Contains: Strontium Renelate…2g
	Diary No. Date of R& I & fee	Dy No. 14441: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other drugs affecting bone structure and mineralization
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Onita Sachet by Pharmevo
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years alongwith Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
788	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Muodart 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin……0.4mg
	Diary No. Date of R& I & fee	Dy No. 14447: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Maxflow Capsule by CCL
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on

		inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
789	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Monofin 125mg Tablet
	Composition	Each Tablet Contains: Terbinafine HCl…125mg
	Diary No. Date of R& I & fee	Dy No. 14450: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 125mg (as hydrochloride) tablet blister pack TGA Australia Approved
	Me-too status	Terbitec Tablet by Fynk Pharma
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	• Firm has initially applied for film coated tablet, later the firm revised formulation to uncoated tablet along with submission of 7,500/- fee.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
790	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Ezicoside 4mg Capsule
	Composition	Each Capsule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy No. 14444: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg, capsule ANSM France Approved
	Me-too status	Thiolax Capsule by S.J&G Fazul Ellahie
	GMP status	Firm has submitted inspection report dated 11-12-2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed

		report concluded that firm has rectified majority of observations and the report is being forwarded to competent authority for resumption of production activities in Oral Liquid Syrup section.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
791	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Surlid 50mg Tablet
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Dy No. 16778: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Solium-50 Tablets by Genome Pharmaceuticals
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise formulation from film coated tablet to uncoated tablet as per the reference product. However, firm has NOT submitted fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
792	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Surlid 200mg Tablet
	Composition	Each Tablet Contains: Amisulpride…200mg
	Diary No. Date of R& I & fee	Dy No. 16779: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Amiride Tablet 200mg by Shrooq Pharmaceuticals
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise formulation from film coated tablet to uncoated tablet as per the reference product. However, firm has NOT submitted fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

793	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Surlid 400mg Tablet
	Composition	Each Tablet Contains: Amisulpride…400mg
	Diary No. Date of R& I & fee	Dy No. 16780: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Amiride Tablet 00mg by Shrooq Pharmaceuticals
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise formulation from film coated tablet to uncoated tablet as per the reference product. However, firm has NOT submitted fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to un-coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
794	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Olmepin 5/20 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine As Besylate…5mg Olmesartan Medoxomil…20mg
	Diary No. Date of R& I & fee	Dy No. 16756: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
795	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Olmepin 10/40 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine As Besylate…10mg Olmesartan Medoxomil…40mg
	Diary No. Date of R& I & fee	Dy No. 16757: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
796	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Telpin 5/40 mg Tablet
	Composition	Each Bilayered Tablet Contains: Amlodipine As Besylate…5mg Telmisartan…40mg
	Diary No. Date of R& I & fee	Dy No. 16758: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Am-Telsan Tablet by Hilton
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has submitted that bilayer tablet compression machine in a phase of purchase.
	Decision: Deferred for submission of evidence of purchase along with IQ, OQ and PQ for the bilayer tablet machine.	
797	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Telpin 10/80 mg Tablet
	Composition	Each Bilayered Tablet Contains: Amlodipine As Besylate…10mg Telmisartan…80mg
	Diary No. Date of R& I & fee	Dy No. 16759: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Am-Telsan Tablet by Hilton
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has submitted that bilayer tablet compression machine in a phase of purchase.
	Decision: Deferred for submission of evidence of purchase along with IQ, OQ and PQ for the bilayer tablet machine.	

798	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Lodisar 5/12.5/160 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine…5mg Hydrochlorothiazide…12.5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 15776: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), other combinations
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Co-Extor Tablet by Searle
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revised the label claim as per follow without submission of full fee of registration: Each Film Coated Tablet Contains: Amlodipine (as besylate)…5mg Hydrochlorothiazide…12.5mg Valsartan…160mg
	Decision: Approved with following label claim: Each Film Coated Tablet Contains: Amlodipine (as besylate)…5mg Hydrochlorothiazide…12.5mg Valsartan…160mg • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 30,000 fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
799	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Rela 8mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…8mg
	Diary No. Date of R& I & fee	Dy No. 16775: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
800	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Rela 16mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…16mg

	Diary No. Date of R& I & fee	Dy No. 16776: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
801	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Rela 24mg Tablet
	Composition	Each Tablet Contains: Betahistine Dihydrochloride…24mg
	Diary No. Date of R& I & fee	Dy No. 16777: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Serc Tablet by Abbott
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
802	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Dobil 500mg Capsule
	Composition	Each Capsule Contains: Calcium Dobesilate As Monohydrate…500mg
	Diary No. Date of R& I & fee	Dy No. 16781: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivaricose Therapy
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxium® 500 mg capsule **Swissmedic** Approved
	Me-too status	Doxium capsule by AGP
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revised label claim as per follow without submission of full fee of registration: Each Capsule Contains: Calcium Dobesilate Monohydrate…500mg
	Decision: Approved with Innovator's specifications and with following label claim:	

	Each Capsule Contains: **Calcium Dobesilate Monohydrate…500mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 30,000 fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
803	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Citawell 500mg/5ml Syrup
	Composition	Each 5ml Syrup Contains: Citicoline As Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 15791: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOMAZINE 100 mg/ml Oral Solution CIMA Spain Approved
	Me-too status	Citicode Syrup by Rotex Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
804	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Clowin 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Clopidogrel As Bisulphate…75mg
	Diary No. Date of R& I & fee	Dy No. 16751: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lowplat tablet by Pharmevo
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
805	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Benz 15mg Capsule
	Composition	Each Extended Release Capsule Contains: Cyclobenzaprine HCl Pellets Eq. To Cyclobenzaprine…15mg
	Diary No. Date of R& I & fee	Dy No. 15764: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Cyclorest ER Capsule by Martin Dow
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	**Source of Pellets:** M/s Vision Pharma, Islamabad. • Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise label claim as per follow without submission of full fee of registration: Each Capsule Contains: Cyclobenzaprine HCl (as extended release pellets)…15mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Cyclobenzaprine HCl (as extended release pellets)…15mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 30,000 fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
806	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Benz 30mg Capsule
	Composition	Each Extended Release Capsule Contains: Cyclobenzaprine Hcl Pellets Eq. To Cyclobenzaprine…30mg
	Diary No. Date of R& I & fee	Dy No. 15765: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Cyclorest ER Capsule by Martin Dow
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	**Source of Pellets:** M/s Vision Pharma, Islamabad. • Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise label claim as per follow without submission of full fee of registration: Each Capsule Contains: Cyclobenzaprine HCl (as extended release pellets)…30mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Cyclobenzaprine HCl (as extended release pellets)……30mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 30,000 fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
807	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Desinaf 50mg Tablet
	Composition	Each Extended Release Tablet Contains: Desvenlafaxine As Succinate…50mg
	Diary No. Date of R& I & fee	Dy No. 16770: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Desven XR Tablet by PharmEvo
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise label claim as per follow without submission of 7500/- fee of registration: Each Extended Release Film Coated Tablet Contains: Desvenlafaxine As Succinate…50mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Extended Release Film Coated Tablet Contains:** **Desvenlafaxine as Succinate…50mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 7,500 fee for revision from uncoated extended release tablet to film coated extended release tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
808	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Desinaf 100mg Tablet
	Composition	Each Extended Release Tablet Contains: Desvenlafaxine As Succinate…100mg
	Diary No. Date of R& I & fee	Dy No. 16771: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Desven XR Tablet by PharmEvo
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise label claim as per follow without submission of 7500/- fee of registration: Each Extended Release Film Coated Tablet Contains: Desvenlafaxine As Succinate…100mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Extended Release Film Coated Tablet Contains:** **Desvenlafaxine as Succinate…100mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm shall submit 7,500 fee for revision from uncoated extended release tablet to film coated extended release tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
809	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Dexiwen 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…200mg
	Diary No. Date of R& I & fee	Dy No. 15784: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tercica Tablet by Sami
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
810	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Dexiwen 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R& I & fee	Dy No. 16746: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tercica Tablet by Sami
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
811	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Dilet 50mg Capsule
	Composition	Each Capsule Contains: Diacerein…50mg
	Diary No. Date of R& I & fee	Dy No. 15798: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diacerein Biogaran 50 mg, capsule ANSM Approved.
	Me-too status	Diora Capsule by Getz
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

812	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Diclolet 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac Potassium…50mg
	Diary No. Date of R& I & fee	Dy No. 16750: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Maxit Tablet by Hilton
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
813	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Domcelium 10mg Tablet
	Composition	Each Tablet Contains: Domperidone…10mg
	Diary No. Date of R& I & fee	Dy No. 15792: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Domel Tablet by Barrett Hodgson
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise label claim as per follow without submission of full fee of registration: Each Tablet Contains: Domperidone (as maleate)…10mg
	Decision: Approved with following label claim: Each Tablet Contains: Domperidone (as maleate)…10mg • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
814	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Doxyfit 100mg/5ml Syrup
	Composition	Each 5ml Syrup Contains: Doxofylline…100mg
	Diary No. Date of R& I & fee	Dy No. 15778: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other Systemic Drugs For Obstructive Airway Diseases
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy Approved
	Me-too status	Unifyline Syrup by Platinum
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
815	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Doxyfit 400mg Tablet
	Composition	Each Tablet Contains: Doxofylline…400mg
	Diary No. Date of R& I & fee	Dy No. 15777: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other Systemic Drugs For Obstructive Airway Diseases
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy Approved
	Me-too status	Xofi Tablet by Hilton
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
816	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Pylit 10/10 mg Tablet
	Composition	Each Delayed Release Film Coated Tablet Contains: Doxylamine Succinate…10mg Pyridoxine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 15779: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Vomifit Tablet by Hilton
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	

	• **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
817	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Dulet 40mg Capsule
	Composition	Each Capsule Contains: Duloxetine HCl As Enteric Coated Pellets Eq. To Duloxetine…40mg
	Diary No. Date of R& I & fee	Dy No. 15799: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad. • Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
818	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Wincet 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram As Oxalate…5mg
	Diary No. Date of R& I & fee	Dy No. 16749: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Citanew Tablet by Hilton
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
819	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Gemlok 320mg Tablet
	Composition	Each Film Coated Tablet Contains: Gemifloxacin Mesylate Eq. To Gemifloxacin…320mg
	Diary No. Date of R& I & fee	Dy No. 16744: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in FDA / applicant withdraw its application for Marketing authorization in EMA
	Me-too status	Gemixa tablet by Bosch Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.

	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
820	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Limet 2mg Tablet
	Composition	Each Tablet Contains: Glimepiride…2mg
	Diary No. Date of R& I & fee	Dy No. 16762: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Econid Tablet by Highnoon
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
821	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Limet 4mg Tablet
	Composition	Each Tablet Contains: Glimepiride…4mg
	Diary No. Date of R& I & fee	Dy No. 16763: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Econid Tablet by Highnoon
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
822	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Ibron 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Ibandronic Acid As Ibandronic Sodium Monohydrate…150mg
	Diary No. Date of R& I & fee	Dy No. 16745: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Ibnate Tablets by Geniz Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
823	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Cardilet 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan…300mg
	Diary No. Date of R& I & fee	Dy No. 16743: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Accord tablet by CCL
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
824	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Ketowin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Ketorolac Tromethamine…10mg
	Diary No. Date of R& I & fee	Dy No. 15785: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Toradol Tablet by Martin Dow
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
825	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Luflet 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Leflunomide…10mg
	Diary No. Date of R& I & fee	Dy No. 16772: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective immunosuppressants (L04AA)
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Leflomid Tablet by Pharmatec
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
826	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Luflet 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Leflunomide…20mg
	Diary No. Date of R& I & fee	Dy No. 16773: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective immunosuppressants (L04AA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Leflomid Tablet by Pharmatec
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
827	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Luflet 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Leflunomide…100mg
	Diary No. Date of R& I & fee	Dy No. 16774: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective immunosuppressants (L04AA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Leflomid Tablet by Pharmatec
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
828	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Vinlevo 125mg/5ml Syrup
	Composition	Each 5ml Syrup Contains: Levofloxacin…125mg
	Diary No. Date of R& I & fee	Dy No. 15794: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) as liquid syrup / solution alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
829	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Vinlevo 250mg/10ml Syrup
	Composition	Each 10ml Syrup Contains: Levofloxacin…250mg
	Diary No. Date of R& I & fee	Dy No. 15795: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) as liquid syrup / solution alongwith registration number, brand name and name of firm. • Firm have applied for Levofloxacin 125mg/5ml Syrup as well as Levofloxacin 250mg/10ml Syrup. Firm submitted that this application is 250mg/5ml (250/10ml is written mistakenly). However in USFDA only 250mg/10ml strength is available.
	Decision: Deferred for following: • **Evidence of applied formulation/drug (Levofloxacin 250mg/5ml Syrup) already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation (Levofloxacin 250mg/5ml Syrup) in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Submission of full fee of registration for correction in composition / label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
830	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Morid 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy No. 16764: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy approved.

	Me-too status	Levide tablet by Swiss Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
831	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Morid 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy No. 16765: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy approved.
	Me-too status	Levide tablet by Swiss Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
832	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Linac 145mcg Capsule
	Composition	Each Capsule Contains: Linaclotide…145mcg
	Diary No. Date of R& I & fee	Dy No. 15793: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other drugs for constipation
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LINZESS® 145mcg (linaclotide LINZESS contains linaclotide-coated beads in hard gelatin capsules.) capsules, USFDA approved.
	Me-too status	
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Reference product contains linaclotide-coated beads in hard gelatin capsules while your applied formulation does not depict use of coated beads. Justification is required in this regard. • Provide source of linaclotide-coated along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported beads).

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else submit stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting within 6 months..	
833	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Sino-H 20/25 mg Tablet
	Composition	Each Tablet Contains: Lisinopril As Dihydrate…20mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy No. 15772: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	ACE inhibitors & Diuretics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Co-Ziscar 20/25mg Tablets by Tabros pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise formulation from film coated to uncoated tablet as per reference product without submission of 7,500/- fee.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years along with Rs. 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
834	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Montin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16752: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Afdol Tablet by AGP
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
835	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Montin 10mg/5ml Syrup
	Composition	Each 5ml Contains: Memantine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 15797: 07-03-2019

		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NAMENDA 2 mg/mL Oral Solution (USFDA Approved)
	Me-too status	Stanza Syrup by Rotex Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Firm has revise label claim as per follow without submission of full fee of registration: Each 5ml Contains: Memantine as HCl…10mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each 5ml Contains:** **Memantine as HCl…10mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years along with Rs. 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
836	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Respiz 5mg Tablet
	Composition	Each Chewable Tablet Contains: Montelukast As Sodium…5mg
	Diary No. Date of R& I & fee	Dy No. 16747: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Respicare Chewable Tablet by Genix
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
837	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Nobilet 2.5mg Tablet
	Composition	Each Tablet Contains: Nebivolol As HCl…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16754: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nebil Tablet by Getz
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.

	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
838	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Nobilet 10mg Tablet
	Composition	Each Tablet Contains: Nebivolol As HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16755: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nebil Tablet by Getz
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
839	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Nimolet 30mg Tablet
	Composition	Each Film Coated Tablet Contains: Nimodipine…30mg
	Diary No. Date of R& I & fee	Dy No. 16753: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nidopin Tablet by Global
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
840	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Vasolex 800mg Tablet
	Composition	Each Film Coated Tablet Contains: Piracetam…800mg
	Diary No. Date of R& I & fee	Dy No. 16748: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nootropil Tablet by M/s GSK
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
841	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Roexi 20mg Tablet
	Composition	Each Dispersible Tablet Contains: Piroxicam Betacyclodextrin Eq. To Piroxicam…20mg
	Diary No. Date of R& I & fee	Dy No. 15789: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MOBILIS D-20 piroxicam 20mg dispersible tablet blister pack TGA Australia Approved
	Me-too status	Pcam dispersible tablet by Martin Dow
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since the reference product approved in TGA Australia is available as Piroxicam instead of Piroxicam Betacyclodextrin.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
842	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Potcit 10mEq Tablet
	Composition	Each Extended Release Tablet Contains: Potassium Citrate…10mEq
	Diary No. Date of R& I & fee	Dy No. 15790: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Mineral Supplements
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lithocit Tablet by Getz
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	

843	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Sital 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin…50mg
	Diary No. Date of R& I & fee	Dy No. 16768: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Tagip tablets by Highnoon
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
844	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Sital 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin…100mg
	Diary No. Date of R& I & fee	Dy No. 16769: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Tagip tablets by Highnoon
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
845	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Terifit 125mg Tablet
	Composition	Each Tablet Contains: Terbinafine As HCl…125mg
	Diary No. Date of R& I & fee	Dy No. 16760: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 125mg (as hydrochloride) tablet blister pack TGA Australia Approved
	Me-too status	Terbitec Tablet by Fynk Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.

	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
846	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Terifit 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine As HCl…250mg
	Diary No. Date of R& I & fee	Dy No. 16761: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 125mg (as hydrochloride) tablet blister pack TGA Australia Approved
	Me-too status	Terbitec Tablet by Fynk Pharma
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
847	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Thiocol 4mg Tablet
	Composition	Each Tablet Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy No. 15796: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM France Approved
	Me-too status	Myolax tablet by Genetics
	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
848	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	T-Zin 4mg Tablet
	Composition	Each Tablet Contains: Tizanidine As HCl…4mg
	Diary No. Date of R& I & fee	Dy No. 15788: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Movax Tablet by Sami

	GMP status	Firm has submitted last inspection report dated 12-10-2017 and 12-12-2017 in which the panel recommended the grant of new DML to the firm.
	Remarks of the Evaluator[3].	• Firm has further submitted that their GMP inspection is planned in November 2022 and they will submit report after inspection.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
849	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winzor 5/20mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine As Besylate…5mg Olmesartan Medoxomil…20mg
	Diary No. Date of R& I & fee	Dy No. 17277: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has initially claimed in house specifications while the product monograph is available in latest edition of USP. Firm has now revised specifications to USP but **NOT** submitted any fee for revision of specifications.
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
850	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winzor 10/20mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine As Besylate…10mg Olmesartan Medoximil…20mg
	Diary No. Date of R& I & fee	Dy No. 17301: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Baritec-A Tablets by Barrett Hodgson
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section:

		• Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has initially claimed in house specifications while the product monograph is available in latest edition of USP. Firm has now revised specifications to USP but **NOT** submitted any fee for revision of specifications.
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
851	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Wareon 40/80/125mg Capsule
	Composition	Each Capsule Contains: Aprepitant…40mg Aprepitant…80mg Aprepitant…125mg
	Diary No. Date of R& I & fee	Dy No. 17278: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiemetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	US FDA approved
	Me-too status	Apritus 125mg Capsule of M/s S.J&G Karachi (Reg.# 074887)
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• We applied for registration of WAREON (Aprepitant) 40, 80 and 125mg on 7 March 2017. Keeping in view of the international/local availability of products in separate packing of each strength, it is humbly requested to please consider our dossier as WAREON (Aprepitant) 125mg Capsule. Revised Form 5 is provided by the firm. • Firm has not submitted fee for revision of formulation
	Decision: Approved with Innovator's specifications and with following label claim: **Each Capsule Contains:** **Aprepitant…125mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
852	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Piprawin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Aripiprazole…10mg
	Diary No. Date of R& I & fee	Dy No. 17282: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsychotics

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Aripaze Tablet by Global
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has initially claimed in house specifications while the product monograph is available in latest edition of USP. Firm has now revised specifications to USP but **NOT** submitted any fee for revision of specifications.
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
853	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Piprawin 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Aripiprazole…15mg
	Diary No. Date of R& I & fee	Dy No. 17275: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Arizole Tablet by Amarant
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has initially claimed in house specifications while the product monograph is available in latest edition of USP. Firm has now revised specifications to USP but **NOT** submitted any fee for revision of specifications.
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
854	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winsatra 10mg Capsule
	Composition	Each Capsule Contains: Atomoxetine (as hydrochloride)…10mg

	Diary No. Date of R& I & fee	Dy No. 17299: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Centrally acting sympathomimetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Moxetin Capsule by Genix
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revised the label claim and added the salt form as hydrochloride. However, firm has **NOT** submitted full fee of registration for revision of salt form and composition.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
855	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winsatra 25mg Capsule
	Composition	Each Capsule Contains: Atomoxetine (as hydrochloride)…25mg
	Diary No. Date of R& I & fee	Dy No. 17303: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Centrally acting sympathomimetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Moxetin Capsule by Genix
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revised the label claim and added the salt form as hydrochloride. However, firm has **NOT** submitted full fee of registration for revision of salt form and composition.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
856	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Baclowin 10mg Tablet
	Composition	Each Tablet Contains:

		Baclofen…10mg
	Diary No. Date of R& I & fee	Dy No. 17294: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Baclofa Tablet by Helix
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
857	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Benza 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cyclobenzaprine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 17285: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	FLEXERIL (5mg, 10mg) film coated tablets USFDA Approved and Discontinued with reason that "Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons"
	Me-too status	Cybem Tablet by Sami Pharma
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
858	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Destine 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 17310: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Destina Tablet by Hilton
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revision the formulation from uncoated to film coated tablet as per reference product. However, firm has **NOT** submitted fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of formulation from uncoated to film coated tablet as per reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
859	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Dexiwin 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R& I & fee	Dy No. 17280: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tercica Tablet by Sami
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
860	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Dulexa 30mg Capsule
	Composition	Each Capsule Contains: Duloxetine HCl (as enteric coated pellets) eq to Duloxetine….30mg
	Diary No. Date of R& I & fee	Dy No. 17302: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	**Source of pellets:** M/s Vision Pharmaceuticals. • Firm has revise the label claim for correction of salt form as per reference product but has **NOT** submitted full fee of registration for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
861	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Dulexa 60mg Capsule
	Composition	Each Capsule Contains: Duloxetine HCl (as enteric coated pellets) eq to Duloxetine ……60mg
	Diary No. Date of R& I & fee	Dy No. 17273: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antidepressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dulan Capsule by Hilton
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	**Source of pellets:** M/s Vision Pharmaceuticals. • Firm has revise the label claim for correction of salt form as per reference product but has **NOT** submitted full fee of registration for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
862	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Eprewin 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Eperisone HCl…50mg
	Diary No. Date of R& I & fee	Dy No. 17292: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Eperisone Hydrochloride Tablets 50mg "TCK" PMDA Japan Approved (Sugar coated tablet)
	Me-too status	Eprisa Tablet by Fynk Pharma
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since the reference product approved by PMDA Japan is as sugar coated tablet.
	Decision: Approved with Innovator's specifications and with following label claim: **Each Sugar Coated Tablet Contains:** **Eperisone HCl…50mg** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
863	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Etroxib 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy No. 17272: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiinflammatory and Antirheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Hetoxib Tablet by Hilton
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
864	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Fexowin 120mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…120mg

	Diary No. Date of R& I & fee	Dy No. 17291: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Fexet Tablets by Getz
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
865	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Fexowin 180mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine Hcl…180mg
	Diary No. Date of R& I & fee	Dy No. 17284: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Fexet Tablets by Getz
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
866	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Iband 150mg Tablet
	Composition	Each film-coated tablet contains: Ibandronic acid (as sodium monohydrate) …150mg
	Diary No. Date of R& I & fee	Dy No. 17297: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ibnate Tablets by Geniz Pharma

	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Reference of finished product specifications. • Firm has revised the label claim along with salt form correction. However, firm has **NOT** submitted full fee for this revision.
	Decision: Approved with Innovator's specification. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
867	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Ketozole 200mg Tablet
	Composition	Each Tablet Contains: Ketoconazole…200mg
	Diary No. Date of R& I & fee	Dy No. 17286: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Danzap Tablet by Hilton
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
868	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Wincam 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy No. 17288: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
	Me-too status	Zafon Tablets by Getz

	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
869	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Mentine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 17274: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other anti-dementia drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Afdol Tablet by AGP
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
870	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Naproflex Plus 500/85mg Tablet
	Composition	Each Film Coated Tablet Contains: Naproxen Sodium…500mg Sumatriptan As Succinate…85mg
	Diary No. Date of R& I & fee	Dy No. 17300: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID and Selective serotonin (5HT1) agonists
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sumanex Tablet by High-Q
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section

		• Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
871	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Setwin 8mg tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron (as hydrochloride Dihydrate)…8mg
	Diary No. Date of R& I & fee	Dy No. 17276: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Danset Tablet by CCL
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with salt form correction. However, firm has **NOT** submitted full fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
872	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Oxitine 37.5mg Tablet
	Composition	Each enteric, film coated, controlled release tablet contains: Paroxetine (as HCl)…37.5mg
	Diary No. Date of R& I & fee	Dy No. 17306: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Seroxat CR Tablet by GSK
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section

		Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has initially applied for film coated tablet later the firm revised its formulation to enteric film coated controlled release tablet. Firm has **NOT** submitted full fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of formulation from film coated tablet to enteric film coated controlled release tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
873	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winquit 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine As Fumarate…100mg
	Diary No. Date of R& I & fee	Dy No. 17293: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Q-Par Tablet by Helix
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
874	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winquit 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine As Fumarate…200mg
	Diary No. Date of R& I & fee	Dy No. 17305: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Q-Par Tablet by Helix
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•

	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
875	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Freetime 50mg Tablet
	Composition	Each film-coated tablet contains: Sertraline (as hydrochloride) …50mg
	Diary No. Date of R& I & fee	Dy No. 17296: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Seralin Tablet by Bosch
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with salt form correction. However, firm has **NOT** submitted full fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
876	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Freetime 100mg Tablet
	Composition	Each film-coated tablet contains: Sertraline (as hydrochloride) …100mg
	Diary No. Date of R& I & fee	Dy No. 17287: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Seralin Tablet by Bosch
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with salt form correction. However, firm has **NOT** submitted full fee for this revision.
	Decision: Approved. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	

	• **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
877	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Wisamet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin As Phospate Monohydrate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 17289: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
878	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Wisamet 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin As Phospate Monohydrate…50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 17304: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	

	• **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
879	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winafin 125mg Tablet
	Composition	Each Film Coated Tablet Contains: Tarbinafine (as HCl)…125mg
	Diary No. Date of R& I & fee	Dy No. 17295: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil Tablet (TGA Approved)
	Me-too status	TBF Tablet by Rotex Pharma
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with salt form correction. However, firm has **NOT** submitted full fee for this revision.
	Decision: Approved with following label claim: Each Tablet Contains: Tarbinafine (as HCl)…125mg • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
880	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Winafin 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Tarbinafine (as HCl)…250mg
	Diary No. Date of R& I & fee	Dy No. 17279: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved
	Me-too status	TBF Tablet by Rotex Pharma
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with salt form correction. However, firm has **NOT** submitted full fee for this revision.
	Decision: Approved with following label claim: Each Tablet Contains:	

	Tarbinafine (as HCl)…250mg • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
881	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Widamet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 17307: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved
	Me-too status	Galmet Tablet by Vision Pharma
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications with a shelf life of 18 months. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
882	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Widamet 50/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy No. 17309: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved
	Me-too status	Galmet Tablet by Vision Pharma
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications with a shelf life of 18 months. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
883	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.**

		Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Widamet 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 17308: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved
	Me-too status	Galmet Tablet by Vision Pharma
	GMP status	Firm has submitted copy of inspection report dated 07-03-2019 in which the panel recommends the renewal of DML for following section: • Tablet (General) Section, • Tablet (Antibiotic) section • Capsule (General) section Firm has also submitted copy of letter for issuance of GMP certificate to QA&LT Division DRAP dated 13-04-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications with a shelf life of 18 months. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
884	**Name and address of manufacturer / Applicant**	**M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Ossorin-D Tablet
	Composition	Each Film Coated Tablet Contains: Vitamin D… 400 IU Ossein Mineral Complex…830mg Corresponding to Calcium…177.6mg Phosphorus…82.2mg Residual Mineral Salts…24.8mg Collagen…224mg Other Proteins…88.4mg Trace Elements… Fi,mg,Fe,Zn,Cu,Ni. Corresponding To Approximately 440mg Hydroxyapatite
	Diary No. Date of R& I & fee	Dy No. 15459: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Minerals / Vitamin
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Osnate-D Tablets by AGP
	GMP status	GMP certificate issued on the basis of inspection dated 12.08.2020

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	Firm submitted that Registration Board already approved the formulation in DRB meeting No. M-295 without any availability of RRA reference for Hilton Pharma Karachi.
2.	Evidence of atomic absorption spectrophotometer used for the analysis of drug product.	Firm has submitted copy of letter dated 27-08-2020 from Rotex Pharma specifying that they have atomic absorption spectrophotometer (Model AA 7000 Brand Shimadzu) available and operating at our factory premises located at plot No. 206 & 207,

				Industrial Triangle Kahuta Road Islamabad. The letter is verified and signed by FID Islamabad dated 01-09-2020.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.			

885.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.**
	Brand Name +Dosage Form + Strength	Oxytide-F Dry Powder Inhaler 50/250mcg
	Diary No. Date of R& I & fee	Diary No: 15332: 15-09-17; PKR: 20,000/-: 15-09-2017 (Duplicate dossier submitted along with relevant page of R&I register)
	Composition	Each Capsule contains: Salmeterol Xinafoate…. 50mcg Fluticasone propionate….250mcg
	Pharmacological Group	Long acting beta-2-adrenoreceptor agonists/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's Specifications
	Pack size & Demanded Price	28's, 60's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ADVAIR DISKUS 250/50 (USFDA Approved)
	Me-too status	Seretide Diskus 50/250mcg of GSK
	GMP status	GMP certificate of M/s Werrick Pharmaceuticals issued on the basis of inspection dated 12-08-2022.
	Remarks of the Evaluator.	Each delivered dose contains: Salmeterol as Xinafoate……..45mcg Fluticasone Propionate……231mcg • The label claim of the applied product is not as per innovator's product, since the applied product contains salmetrol xinafoate while innovator's product provides label claim and delivered dose for salmetrol base. Firm has not revised its claim or submitted any fee. • Firm has claimed in house specs while USP mmonograph of applied product is available.
	Decision: Approved with USP specifications and with following label claim: **Each Capsule contains:** **Salmeterol as Xinafoate…. 50mcg** **Fluticasone propionate….250mcg** • **Registration Board further decided that following label claim of delivered dose shall be declared on registration letter:** **"Each delivered dose contains:** **Salmeterol as Xinafoate……..45mcg** **Fluticasone Propionate……231mcg"** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

886.	**Name and address of manufacturer / Applicant**	**M/s Wilson's Pharmaceuticals.** **387-388, I-9, Industrial Area, Islamabad**
	Brand Name +Dosage Form + Strength	Coldene Pro XR Tablet 60/120mg
	Composition	Each Extended Release Film Coated Tablet Contains: Fexofenadine HCl…60mg Pseudoephedrine HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 16637: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use - Nasal decongestant

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved (Over-the-counter drug) as bilayer tablet Telfast Decongestant Tablet (TGA Approved) Bi-layer, capsule shaped, film coated tablets
	Me-too status	Telfast D Tablet by Sanofi Aventis
	GMP status	GMP certificate issued on basis of inspection conducted on 28-07-2022.
	Remarks of the Evaluator[3].	• Firm has revised the formulation along with submission of full fee PKR 30,000/- vide slip number 0898320516 dated 23-11-2022. The revised label claim of the firm is as under: Each bi-layer extended release film coated tablet contains: Fexofenadine HCl……60mg Pseudoephedrine HCl…..120mg • Firm has submitted that the bilayer composition our our product Teli-H 40/12.5mg Tablet was also approved in 321st RB meeting.
	Decision: Approved with USP specifications and with following label claim: **Each bi-layer extended release film coated tablet contains:** **Fexofenadine HCl……60mg** **Pseudoephedrine HCl…..120mg**	
887.	**Name and address of manufacturer / Applicant**	**M/s Wilson's Pharmaceuticals.** **387-388, I-9, Industrial Area, Islamabad**
	Brand Name +Dosage Form + Strength	Wiscon Suspension 500/213/325mg
	Composition	Each 10ml Suspension Contains: Sodium Alginate…500mg Sodium Bicarbonate…213mg Calcium Carbonate….325mg
	Diary No. Date of R& I & fee	Dy No. 16640: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Gaviscon Double Action Aniseed (MHRA Approved)
	Me-too status	Lagita Double Action Suspension by Sami
	GMP status	GMP certificate issued on basis of inspection conducted on 28-07-2022.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. **Firm has submitted that stability study data of the applied product is under stability studies and they will submit the data as soon as it is complete.**
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
888.	**Name and address of manufacturer / Applicant**	**M/s Wilson's Pharmaceuticals.** **387-388, I-9, Industrial Area, Islamabad**
	Brand Name +Dosage Form + Strength	Wiscon Chewable Tablets 200/200/25mg
	Composition	Each Chewable Tablet Contains: Aluminium hydroxide Gel (dried)…200mg Magnesium hydroxide…200mg Simethicone…….25mg
	Diary No. Date of R& I & fee	Dy No. 16639: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Maalox Plus Chewable Tablets 200mg/200mg/25mg (**HPRA Ireland** Approved) Chewable Tablet.

		Bi-layered, white/yellow tablets engraved with"Maalox" on oneside.
	Me-too status	Trisil plus tablet of Efroze
	GMP status	GMP certificate issued on basis of inspection conducted on 28-07-2022.
	Remarks of the Evaluator[3].	• The HPRA Ireland approved tablet is available as chewable bilayer tablet while firm has applied for chewable tablet.
	Decision: Approved with USP specifications and with following label claim: **Each Chewable bi-layer Tablet Contains:** **Aluminium hydroxide Gel (dried)…200mg** **Magnesium hydroxide…200mg** **Simethicone…….25mg** • **Firm will submit 30,000/- fee for revision in formulation as per reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
889.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad**
	Brand Name +Dosage Form + Strength	Flueze Pro XR Tablet 60/120mg Tablet
	Composition	Each Extended Release Film Coated Tablet Contains: Fexofenadine HCl…60mg Pseudoephedrine HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 16634: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use - Nasal decongestant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved (Over-the-counter drug) as bilayer tablet Telfast Decongestant Tablet (TGA Approved) Bi-layer, capsule shaped, film coated tablets
	Me-too status	Telfast D Tablet by Sanofi Aventis
	GMP status	GMP certificate issued on basis of inspection conducted on 12-8-2022
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Reference product is available as a bilayer extended release film coated tablet, revise your label claim as per the reference product. • Evidence of bilayer tablet machine
	Decision: Approved with USP specifications and with following label claim: **Each bi-layer extended release film coated tablet contains:** **Fexofenadine HCl……60mg** **Pseudoephedrine HCl…..120mg** • **Firm will submit 30,000/- fee for revision in formulation as per reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Firm will submit evidence of "IQ,OQ & PQ reports of "Bi-layer tablet compression machine" before issuance of Registration letter.**	
890.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd.** **124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Petronel Injection 1MIU
	Composition	Each Vial Contains: Colistimethate Sodium…1MIU
	Diary No. Date of R& I & fee	Dy No. 16690: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Colimixin Injection by Genix Pharma

	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	• Firm has submitted copy of letter of grant of additional section specifying Dry powder injection (General) section.
	Decision: Approved. Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
891.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Zune 20mg capsule
	Composition	Each Delayed Release Capsule Contains: Esomeprazole As Magnesium Trihydrate…20mg
	Diary No. Date of R& I & fee	Dy No. 15960: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nexum capsule by Getz
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	• Source of pellets: M/s Vision Pharmaceuticals, Islamabad. • Firm has revised the label claim as per the following along with submission of Fee PKR 7,500/-. The revised label claim is as under: Each Capsule Contains: Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…20mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…20mg** • **Firm will submit 22,500/- balance fee for revision in formulation as per reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
892.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Zune 40mg Capsule
	Composition	Each Delayed Release Capsule Contains: Esomeprazole As Magnesium Trihydrate…40mg
	Diary No. Date of R& I & fee	Dy No. 15961: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nexum capsule by Getz
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	• Source of pellets: M/s Vision Pharmaceuticals, Islamabad. • Firm has revised the label claim as per the following along with submission of Fee PKR 7,500/-. The revised label claim is as under:

		Each Capsule Contains: Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…40mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…40mg** • **Firm will submit 22,500/- balance fee for revision in formulation as per reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
893.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Aidra 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Leflunomide…10mg
	Diary No. Date of R& I & fee	Dy No. 15957: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective immunosuppressants (L04AA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Leflomid Tablet by Pharmatec
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
894.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Lavitam 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Dy No. 15954: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
895.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Lavitam 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 15955: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lumark Tablet by Searle
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
896.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Lavitam Injection 500mg/5ml
	Composition	Each 5ml Contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 15956: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 100 mg / mL Concentrate for solution for infusion (MHRA Approved)
	Me-too status	Lumark Injection by Searle
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	• Firm has submitted copy of letter of grant of additional section specifying Liquid injection (General) section.
	Decision: Approved with Innovator's specifications.	
897.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Ambron Tablet 400mg
	Composition	Each Delayed Release Tablet Contains: Mesalamine…400mg
	Diary No. Date of R& I & fee	Dy No. 15953: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Colinil Tablet by Novamed
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications.	
898.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Benzim Tablet 20mg
	Composition	Each Delayed Release Tablet Contains: Omeprazole…20mg
	Diary No. Date of R& I & fee	Dy No. 15958: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zulcid Tablet by Shrooq
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	•
	Decision: Deferred for evidence of availability of requisite manufacturing facilities/technology in line with reference product for multiple unit pllets system (MUPS).	
899.	**Name and address of manufacturer / Applicant**	**M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Benzim capsule 40mg
	Composition	Each Delayed Release Capsule Contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy No. 15959: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nexum capsule by Getz
	GMP status	Firm has submitted copy of GMP inspection report dated 13-09-2022 and 14-09-2022 ehich concludes that the firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator[3].	• Source of pellets: M/s Vision Pharmaceuticals, Islamabad. • Firm has revised the label claim as per the following along with submission of Fee PKR 7,500/-. The revised label claim is as under: Each Capsule Contains: Omeprazole (as enteric coated pellets)…40mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Omeprazole (as enteric coated pellets)…40mg** • **Firm will submit 22,500/- balance fee for revision in formulation as per reference product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
900.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Vastdip 5/10 mg Tablet
	Composition	Each Tablet Contains: Amlodipine As Besylate…5mg Atorvastatin As Calcium Trihydrate…10mg
	Diary No. Date of R& I & fee	Dy No. 17125: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Lipifal Tablet by Helix
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved.	

	• **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
901.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Vastdip 10/10 mg Tablet
	Composition	Each Tablet Contains: Amlodipine As Besylate…10mg Atorvastatin As Calcium Trihydrate…10mg
	Diary No. Date of R& I & fee	Dy No. 17163: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Lipifal Tablet by Helix
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
902.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Amsoar 5/80 mg Tablet
	Composition	Each Tablet Contains: Amlodipine As Besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 17132: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
903.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Amosar 5/160 mg Tablet
	Composition	Each Tablet Contains:

		Amlodipine Besylate…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 17174: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
904.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Amsoar 10/160 mg Tablet
	Composition	Each Tablet Contains: Amlodipine As Besylate…10mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy No. 17161: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
905.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Clofen 10mg Tablet
	Composition	Each Tablet Contains: Baclofen…10mg
	Diary No. Date of R& I & fee	Dy No. 17162: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Baclofa Tablet by Helix
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
906.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Sloradin 5mg Tablet
	Composition	Each Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 17127: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Destina Tablet by Hilton
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
907.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Stin 10mg Tablet
	Composition	Each Tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Dy No. 17124: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Netherland Approved.
	Me-too status	Kestine Tablet by Highnoon
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee. • You have applied in house specifications while the product monograph is available in JP. Revise your specifications along with submission of applicable fee.
	Decision: Approved with JP specifications.	

	• **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
908.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Talopra 5mg Tablet
	Composition	Each Tablet Contains: Escitalopram As Oxalate…5mg
	Diary No. Date of R& I & fee	Dy No. 17157: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Citanew Tablet by Hilton
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
909.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Talopra 10mg Tablet
	Composition	Each Tablet Contains: Escitalopram As Oxalate…10mg
	Diary No. Date of R& I & fee	Dy No. 17152: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Citanew Tablet by Hilton
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
910.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Zepa-Mark 1mg Tablet
	Composition	Each Tablet Contains: Lorazepam…1mg
	Diary No. Date of R& I & fee	Dy No. 17143: 07-03-2019

		PKR 20,000/-: 06-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lorapram tablet by Hiranis
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of psychotropic tablet section from Licensing Division DRAP.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
911.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Zepa-Mark 2mg Tablet
	Composition	Each Tablet Contains: Lorazepam…2mg
	Diary No. Date of R& I & fee	Dy No. 17181: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lorapram tablet by Hiranis
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of psychotropic tablet section from Licensing Division DRAP.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	
912.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Losat-P 25mg Tablet
	Composition	Each Tablet Contains: Losartan Potassium…25mg
	Diary No. Date of R& I & fee	Dy No. 17171: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Xavor Tablet by Ferozesons
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved.	

	• **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
913.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Losat-P 50mg Tablet
	Composition	Each Tablet Contains: Losartan Potassium…50mg
	Diary No. Date of R& I & fee	Dy No. 17158: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Xavor Tablet by Ferozesons
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to film coated tablet as per the reference product along with submission of applicable fee.
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
914.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Mecoman 500mcg Tablet
	Composition	Each Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy No. 17131: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Vitamin B12 analogue
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Methycobal tablet by Hilton
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to sugar coated tablet as per the reference product along with submission of applicable fee. • You have applied in house specifications while the product monograph is available in JP. Revise your specifications along with submission of applicable fee.
	Decision: Approved with JP Specifications. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	
915.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Melodem 7.5mg Tablet

	Composition	Each Tablet Contains: Meloxicam…7.5mg
	Diary No. Date of R& I & fee	Dy No. 17133: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Melor Tablet by Sami
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
916.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Melodem 15mg Tablet
	Composition	Each Tablet Contains: Meloxicam…15mg
	Diary No. Date of R& I & fee	Dy No. 17129: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Melor Tablet by Sami
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.	
917.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Phenidate 10mg Tablet
	Composition	Each Tablet Contains: Methylphenidate HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 17156: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Centrally acting sympathomimetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ritalin Tablet by Novartis
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of psychotropic tablet section from Licensing Division DRAP.
	Decision: Deferred for confirmation of required manufacturing facility / section from Licensing Division.	

918.	**Name and address of manufacturer / Applicant**	**M/s Medimarker's Labortaries Pvt Ltd A-104, S.I.T.E Area, Hyderabad**
	Brand Name +Dosage Form + Strength	Moximed 400mg Tablet
	Composition	Each Tablet Contains: Moxifloxacin Hcl…400mg
	Diary No. Date of R& I & fee	Dy No. 17128: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Avelox Tablet by Bayer
	GMP status	Last GMP inspection of conducted on 16-10-2018 and the report concludes that the panel unanimously recommend the grant of renewal DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation as per the reference product along with submission of full fee. The revised label claim shall be "Each film coated tablet contains: Moxifloxacin as hydrochloride….400 mg"
	Decision: Approved. • **Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of latest GMP inspection report conducted within last three years.**	

c. New cases in which stability study data is required

919.	**Name and address of manufacturer / Applicant**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Brand Name +Dosage Form + Strength	Denset 2mg Tablet
	Composition	Each Uncoated Tablet Contains: Dienogest…2mg
	Diary No. Date of R& I & fee	Dy No. 14565: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Progestogens
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

		• Evidence of requisite manufacturing facility / section approval from Licensing Division.
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Evidence of requisite manufacturing facility / section approval from Licensing Division.** • **Reference of finished product specifications.**	
920.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Sofvel 400/100 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sofosbuvir…400mg Velpatasvir…100mg
	Diary No. Date of R& I & fee	Dy No. 15786: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivirals for treatment of HCV infections
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Fosbu V Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

921.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Dapazin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin…10mg
	Diary No. Date of R& I & fee	Dy No. 15780: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Daploz Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Three batches data submitted to DRAP
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.
3.	Revise your label claim as per the reference product along with submission of requisite fee.	Stability has been conducted as per the reference product (Forxiga 10mg Tablet)

	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
922.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Canazin 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin…300mg
	Diary No. Date of R& I & fee	Dy No. 15782: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Glucana Tablet by CCL
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

923.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Canazin-M 150/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Canagliflozin…150mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy No. 15783: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	CGZin M Tablet by Helix
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

924.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Azitan 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Azilsartan Medoxomil Potassium Eq. To Azilsartan Medoxomil As Potassium…80mg
	Diary No. Date of R& I & fee	Dy No. 15766: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	N/A
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.
3.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	No response submitted by the firm
4.	Application on Form 5D along with differential fee	No response submitted by the firm

Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.

925.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Azitan-C 40/25 mg Tablet
	Composition	Each Film Coated Tablet Contains: Azilsartan Medoxomil Potassium Eq. To Azilsartan Medoxomil As Potassium…40mg Chlorthalidone…25mg
	Diary No. Date of R& I & fee	Dy No. 15767: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	N/A
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.
3.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	No response submitted by the firm
4.	Application on Form 5D along with differential fee	Application is already submitted on Form 5D, differential fee will be submitted soon.

Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.

926.	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd. Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Hepwin 400/100mg Tablet
	Composition	Each Film Coated Tablet Contains: Sofosbuvir…100mg Valpatasvir…400mg
	Diary No. Date of R& I & fee	Dy No. 17298: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivirals for treatment of HCV infections
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Fosbu V Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
927.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Brand Name +Dosage Form + Strength	Zenwo 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…5mg
	Diary No. Date of R& I & fee	Dy No. 14189: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Daploz Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
928.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Brand Name +Dosage Form + Strength	Zenwo 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin As Propanediol Monohydrate…10mg
	Diary No. Date of R& I & fee	Dy No. 14190: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Daploz Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
929.	**Name and address of manufacturer / Applicant**	**M/s Vision Pharmaceuticals.** **Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Kalset 30mg Tablet
	Composition	Each Tablet Contains: Cinacalcet Hcl Eq To Cinacalcet…30mg
	Diary No. Date of R& I & fee	Dy No. 13946: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other anti-parathyroid agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Mimcipar Tablet by Genome
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim to film coated tablet as per the reference product along with submission of requisite fee.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
930.	**Name and address of manufacturer / Applicant**	**M/s Vision Pharmaceuticals.** **Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Kalset 60mg Tablet
	Composition	Each Tablet Contains: Cinacalcet Hcl Eq To Cinacalcet…60mg
	Diary No. Date of R& I & fee	Dy No. 13947: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other anti-parathyroid agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Mimcipar Tablet by Genome
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim to film coated tablet as per the reference product along with submission of requisite fee.
	Decision: Deferred for following submissions:	

	• **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
931.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Raflozin Tablets 5mg
	Composition	Each Tablet Contains: Dapagliflozin Propanediol …5mg
	Diary No. Date of R& I & fee	Dy No. 16254: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Daploz Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee. • You have mentioned Dapagliflozin Propanediol alone as API in the label claim, while also mentioned metformin in some sections. Clarify about the exact formulation applied in this application.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
932.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd.** **97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Raflozin Tablets 10mg
	Composition	Each Tablet Contains: Dapagliflozin Propanediol …10mg
	Diary No. Date of R& I & fee	Dy No. 16255: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Daploz Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee. • You have mentioned Dapagliflozin Propanediol alone as API in the label claim, while also mentioned metformin in some sections. Clarify about the exact formulation applied in this application.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

	• **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
933.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Obicol 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Obeticholic Acid…5mg
	Diary No. Date of R& I & fee	Dy No. 13629: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Obliva Tablet by Hilton
	GMP status	Firm has submitted copy of GMP certificate issued on 27-07-2021 based on inspection dated 26-05-2021 and 07-07-2021.
	Remarks of the Evaluator[3].	

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Firm has submitted an undertaking that they will submit the stability data before manufacturing any commercial batch and will not sale before submission of stability data. **Firm has not submitted stability study data.**
2.	Latest GMP inspection report conducted within a period of last three years.	Firm has submitted copy of GMP certificate issued on 27-07-2021 based on inspection dated 26-05-2021 and 07-07-2021.

	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
934.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Dpax M 5/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq To Dapagliflozin…5mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy No. 15015: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Daplozmet Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
935.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Dpax M 5/1000mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Dapagliflozin Propanediol Monohydrate Eq To Dapagliflozin…5mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15014: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Daplozmet Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
936.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Velpasof 400/100 mg Tablet
	Composition	Each Capsule Contains: Sofosbuvir…400mg Velpatasvir…100mg
	Diary No. Date of R& I & fee	Dy No. 14245: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivirals for treatment of HCV infections
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• You have mentioned tablet in the brand name and the label claim is provided for capsule dosage form. Clarification is required in this regard. • Evidence of approval of applied formulation as capsule dosage form in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug as capsule dosage form already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • In case your applied formulation is Tablet, submit stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting along with submission of full fee of registration and revised Form 5. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	

	• **Reference of finished product specifications.**	
937.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Omamor Tablet 12.5mg
	Composition	Each Capsule Contains: Omarigliptin…12.5mg
	Diary No. Date of R& I & fee	Dy No. 14251: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• You have mentioned tablet in the brand name and the label claim is provided for capsule dosage form. Clarification is required in this regard. • Evidence of approval of applied formulation as capsule dosage form in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug as capsule dosage form already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • In case your applied formulation is Tablet, submit stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting along with submission of full fee of registration and revised Form 5. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
938.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Omamor Tablet 25mg
	Composition	Each Capsule Contains: Omarigliptin…25mg
	Diary No. Date of R& I & fee	Dy No. 14250: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• You have mentioned tablet in the brand name and the label claim is provided for capsule dosage form. Clarification is required in this regard.

		• Evidence of approval of applied formulation as capsule dosage form in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug as capsule dosage form already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • In case your applied formulation is Tablet, submit stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting along with submission of full fee of registration and revised Form 5. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
939.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Tiger 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Ticagrelor…60mg
	Diary No. Date of R& I & fee	Dy No. 15787: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Platelet aggregation inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Hitica Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

940.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals.** **Plot # 31& 32 Punjab Small Industrial Estate Taxila**
	Brand Name +Dosage Form + Strength	Weglor 90mg tablet
	Composition	Each Film Coated Tablet Contains: Ticagrelor…90mg
	Diary No. Date of R& I & fee	Dy No. 14191: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Platelet aggregation inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Hitica Tablet by Highnoon

	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
941.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Cabisar 24/26 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril…24mg Valsartan…26mg
	Diary No. Date of R& I & fee	Dy No. 15773: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

942.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Cabisar 49/51 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg
	Diary No. Date of R& I & fee	Dy No. 15774: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

943.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**

	Brand Name +Dosage Form + Strength	Cabisar 97/103 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril…97mg Valsartan…103mg
	Diary No. Date of R& I & fee	Dy No. 15775: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	API material procurement is in progress
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

944.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila**
	Brand Name +Dosage Form + Strength	Wencuval 24/26 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex…24.3mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…25.7mg
	Diary No. Date of R& I & fee	Dy No. 14098: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
945.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila**
	Brand Name +Dosage Form + Strength	Wencuval 49/51 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex…48.6mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…51.4mg

	Diary No. Date of R& I & fee	Dy No. 14099: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
946.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals.** **Plot # 31& 32 Punjab Small Industrial Estate Taxila**
	Brand Name +Dosage Form + Strength	Wencuval 97/103 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sacubitril As Sacubitril Valsartan Sodium Salt Complex…97.2mg Valsartan As Sacubitril Valsartan Sodium Salt Complex…102.8mg
	Diary No. Date of R& I & fee	Dy No. 14100: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sacuvia Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
947.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Valbitril Capsule 24/26mg
	Composition	Each Capsule Contains: Sacubitril…24mg Valsartan…26mg
	Diary No. Date of R& I & fee	Dy No. 14221: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
948.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Valbitril Capsule 49/51mg
	Composition	Each Capsule Contains: Sacubitril…49mg Valsartan…51mg
	Diary No. Date of R& I & fee	Dy No. 14220: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
949.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Valbitril Capsule 97/103mg
	Composition	Each Capsule Contains: Sacubitril…97mg

		Valsartan…103mg
	Diary No. Date of R& I & fee	Dy No. 14219: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
950.	**Name and address of manufacturer / Applicant**	**M/s Zeta Pharmaceuticals.** **Plot # 494-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zempa M 5/500mg Tablet
	Composition	Each Tablet Contains: Empagliflozin…5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy No. 15993: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Revise your label claim as per the reference product to film coated tablet along with submission of requisite fee.
	Decision: Deferred for following submissions: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

951.	**Name and address of manufacturer / Applicant**	**M/s Zeta Pharmaceuticals.** **Plot # 494-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zempa M 12.5/1000mg Tablet
	Composition	Each Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15994: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Revise your label claim as per the reference product to film coated tablet along with submission of requisite fee.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
952.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Empazin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy No. 15768: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Three batches data submitted to DRAP dated 7th July 2022.
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
953.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals.** **30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Empazin 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy No. 15769: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Three batches data submitted to DRAP dated 7th July 2022.
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

954.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Empazin-M 5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15770: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Three batches data will be submitted within 4 months.
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.
3.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	Diampa-M Tablets by Getz

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

955.	**Name and address of manufacturer / Applicant**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Brand Name +Dosage Form + Strength	Empazin-M 12.5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15771: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon

	GMP status	

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Three batches data will be submitted within 4 months.
2.	Latest GMP inspection report conducted within a period of last three years.	Inspection report will be submitted within 1 month.
3.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	Diampa-M Tablets by Getz

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

956.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Brand Name +Dosage Form + Strength	Xempo 5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 14101: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Stability data already submitted on 08-06-2022
2.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	Xenglu-Met Tablets by Getz

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

957.	**Name and address of manufacturer / Applicant**	**M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Brand Name +Dosage Form + Strength	Xempo-Wen 12.5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 14102: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon

	GMP status	Last Inspection Report dated 15-06-2022, panel concludes that the firm is operating at good level of GMP compliance.

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Stability data already submitted on 08-06-2022
2.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm	Xenglu-Met Tablets by Getz

Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.

958.	**Name and address of manufacturer / Applicant**	**M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K**
	Brand Name +Dosage Form + Strength	Wefloz-10 mg Tablet
	Composition	Each Tablet Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy No. 16931: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product to film coated tablet along with submission of requisite fee.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
959.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Valoglif 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin.…10mg
	Diary No. Date of R& I & fee	Dy No. 13743: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.

	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
960.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Valoglif 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin.…25mg
	Diary No. Date of R& I & fee	Dy No. 13742: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
961.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Glifmet 5/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin...5mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy No. 13744: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
962.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Glifmet 5/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin...5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 13745: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
963.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Glifmet 12.5/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy No. 13746: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
964.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Glifmet 12.5/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy No. 13747: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
965.	**Name and address of manufacturer / Applicant**	**M/s Valor Pharmaceuticals.** **124/A Industrial Triangle, Kahuta Road Islamabad**
	Brand Name +Dosage Form + Strength	Glifmet 12.5/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 13748: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
966.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals Pvt Limited.** **8 km, Thoker Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Diflozin 10mg Tablet
	Composition	Each Tablet Contains: Empagliflozin …10mg
	Diary No. Date of R& I & fee	Dy No. 16329: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	The firm was inspected on 25-03-2019 and Conclusion of inspection was: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of inspection M/s Trigon Pharmaceuticals Pvt Ltd Lahore was considered to be operating at a satisfactory level of GMP compliance with refrence to GMP guidelines as per Dugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee.

	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
967.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals Pvt Limited.** **8 km, Thoker Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Flomet 5/500mg Tablet
	Composition	Each Tablet Contains: Empagliflozin…5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy No. 16063: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	The firm was inspected on 25-03-2019 and Conclusion of inspection was: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of inspection M/s Trigon Pharmaceuticals Pvt Ltd Lahore was considered to be operating at a satisfactory level of GMP compliance with refrence to GMP guidelines as per Dugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
968.	**Name and address of manufacturer / Applicant**	**M/s Trigon Pharmaceuticals Pvt Limited.** **8 km, Thoker Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Flomet 12.5/1000mg Tablet
	Composition	Each Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 16059: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	The firm was inspected on 25-03-2019 and Conclusion of inspection was: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of inspection M/s Trigon Pharmaceuticals Pvt Ltd Lahore was considered to be operating at a satisfactory level of

		GMP compliance with refrence to GMP guidelines as per Dugs Act, 1976 and rules framed there under.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
969.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd.** **12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Epax M 5mg/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 15013: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
970.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd.** **12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Epax M 5mg/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy No. 15010: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.

	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
971.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Epax M 5mg/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15009: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
972.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Epax M 12.5mg/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy No. 15012: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
973.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Epax M 12.5mg/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…850mg
	Diary No. Date of R& I & fee	Dy No. 15011: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
974.	**Name and address of manufacturer / Applicant**	**M/s Pharma Lord (Pvt) Ltd. 12 KM, Lahore Raod, Layyah, Punjab**
	Brand Name +Dosage Form + Strength	Epax-M 12.5/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15008: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard-M Tablet by Highnoon
	GMP status	GMP certificate issued based on inspection dated 03-05-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
975.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**

	Brand Name +Dosage Form + Strength	Empamor 10mg Capsule
	Composition	Each Capsule Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy No. 14235: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
976.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Empamor M Capsule 5/500mg
	Composition	Each Capsule Contains: Empagliflozin…5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy No. 14232: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	

977.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Empamor M XR Capsule 5/1000mg
	Composition	Each Capsule Contains: Empagliflozin…5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 14233: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
978.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Empamor M XR Capsule 12.5/500mg
	Composition	Each Capsule Contains: Empagliflozin…12.5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy No. 14230: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-**	

	D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board. • **Reference of finished product specifications.**	
979.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals.** **35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Empamor M XR Capsule 12.5/1000mg
	Composition	Each Capsule Contains: Empagliflozin…12.5mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 14231: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diajard Tablet by Highnoon
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since you have applied capsule dosage form while the reference product is available as tablet. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.** • **Reference of finished product specifications.**	
980.	**Name and address of manufacturer / Applicant**	**M/s Zeta Pharmaceuticals.** **Plot # 494-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zelanso capsule 30mg
	Composition	Each Capsule Contains: Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 15995: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

	• **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
981.	**Name and address of manufacturer / Applicant**	**M/s Zeta Pharmaceuticals.** **Plot # 494-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zelanso capsule 60mg
	Composition	Each Capsule Contains: Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy No. 15996: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
982.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd.** **641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Dexazole 30mg Capsule
	Composition	Each Capsule contains: Enteric Coated Pellets Dexlansoprazole Eq To 30mg
	Diary No. Date of R& I & fee	Dy No. 16406: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
983.	**Name and address of manufacturer / Applicant**	**M/s Zamko Pharmaceuticals (Pvt) Ltd.** **641-A Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Dexazole 60mg Capsule
	Composition	Each Capsule contains: Enteric Coated Pellets Dexlansoprazole Eq To 60mg
	Diary No. Date of R& I & fee	Dy No. 16405: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	Inspection date 13/07/2018, panel recommend grant of DML
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
984.	**Name and address of manufacturer / Applicant**	**M/s Winthrox Laboratories Pvt Ltd.** **K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lanso Capsule 30mg
	Composition	Each Capsule Contains: Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 14802: 07-03-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	Last inspection report dated 31-01-2022 concludes that the overall GMP compliance level is rated as good.

Remarks of the Evaluator[3].

Sr. No	Observation	Response by the firm
1.	Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	Firm has submitted stability data sheet only. No other data as per the checklist approved by the Board in 293rd meeting is submitted.
2.	Revise your label claim as per the reference product along with submission of requisite fee.	Firm has submitted revised form 5 however the submitted label claim is still not as per the innovator's product. Furthermore no fee for revision of label claim is submitted.

	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
985.	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Wexcillant 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Enteric Coated…30mg
	Diary No. Date of R& I & fee	Dy No. 17281: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	GMP certificate issued on 15-07-2019 on the basis of inspection conducted on 07-03-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
986.	**Name and address of manufacturer / Applicant**	**M/s Winilton Pharmaceuticals Pvt Ltd.** **Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Wexcillant 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Enteric Coated…60mg
	Diary No. Date of R& I & fee	Dy No. 17282: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	GMP certificate issued on 15-07-2019 on the basis of inspection conducted on 07-03-2019.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
987.	**Name and address of manufacturer / Applicant**	**M/s Webrose Pharmaceuticals.** **Plot # 1, Street # 10, National Industrial Zone, Rawat, Pakistan**
	Brand Name +Dosage Form + Strength	Reaktif 30mg Capsule
	Composition	Each Capsule Contains: Enteric Coated Pellets Of Dexlansoprazole Eq. To Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 15034: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	

	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Copy of valid Drug Manufacturing License (DML) along with evidence of Capsule (General) Section approved by Licensing Division DRAP. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
988.	**Name and address of manufacturer / Applicant**	**M/s Webrose Pharmaceuticals.** **Plot # 1, Street # 10, National Industrial Zone, Rawat, Pakistan**
	Brand Name +Dosage Form + Strength	Reaktif 60mg Capsule
	Composition	Each Capsule Contains: Enteric Coated Pellets Of Dexlansoprazole Eq. To Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy No. 15037: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Copy of valid Drug Manufacturing License (DML) along with evidence of Capsule (General) Section approved by Licensing Division DRAP. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
989.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions Pvt Ltd.** **1.5 km, Manga Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Dexlans 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 14046: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	DML renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025

	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
990.	**Name and address of manufacturer / Applicant**	**M/s Searle IV Solutions Pvt Ltd.** **1.5 km, Manga Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Dexlans 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy No. 14045: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	DML renewal inspection conducted on 02.03.2021 and renewed the DML up to 2025
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
991.	**Name and address of manufacturer / Applicant**	**M/s Panacea Pharmaceuticals.** **Plot. No. 4, Street No. S-6, National Industrial zone Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Dexsole 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets Eq. To Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 13701: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	GMP certificate issued dated 20th October,2020
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	

992.	**Name and address of manufacturer / Applicant**	**M/s Panacea Pharmaceuticals.** **Plot. No. 4, Street No. S-6, National Industrial zone Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Dexsole 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets Eq. To Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy No. 13702: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	GMP certificate issued dated 20th October,2020
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
993.	**Name and address of manufacturer / Applicant**	**M/s Moon Pharmaceuticals** **Plot No. 5, SS-4 Road, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	D Lanso 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole As Enteric Coated Pellets Eq To Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 14446: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	Copy of inspection report dated 11-12-2019 wherein the firm is operating at an acceptable level of GMP.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
994.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharmacal Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	Dexlan Capsule 30mg
	Composition	Each Capsule Contains: Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 13824: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for following submissions: • **Revision of the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Stability study data as per the guidelines provided in 293rd meeting of Registration Board.**	
995.	**Name and address of manufacturer / Applicant**	**M/s Medisave Pharmaceuticals.** **Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Dexisave 60mg capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayed Release Pellets Eq To Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy No. 14973: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Razodex Capsule of Getz
	GMP status	GMP certificate issued to M/s Medisave Pharmaceuticals dated 01-10-2021 based on inspection conducted on 18-09-2021.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
996.	**Name and address of manufacturer / Applicant**	**M/s Medisave Pharmaceuticals.** **Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Empazon 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…10mg
	Diary No. Date of R& I & fee	Dy No. 16588: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diampa Tablet by Getz
	GMP status	GMP certificate issued to M/s Medisave Pharmaceuticals dated 01-10-2021 based on inspection conducted on 18-09-2021.

	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	
997.	**Name and address of manufacturer / Applicant**	**M/s Medisave Pharmaceuticals. Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Empazon 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…25mg
	Diary No. Date of R& I & fee	Dy No. 16589: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Diampa Tablet by Getz
	GMP status	GMP certificate issued to M/s Medisave Pharmaceuticals dated 01-10-2021 based on inspection conducted on 18-09-2021.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of stability study data as per the guidelines provided in 293rd meeting of Registration Board.	

d. Deferred cases

998.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.**
	Brand Name +Dosage Form + Strength	BUD-AIR Dry Powder Inhaler 100/6mcg
	Diary No. Date of R& I & fee	Diary No: 15336: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Budesonide…. 100mcg Formoterol fumarate….6mcg
	Pharmacological Group	Long acting beta-2-adrenoreceptor agonists/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	30‘s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Canada (MHRA)
	Me-too status	Venticort Rotacaps 100mcg+6mcg Capsule of Macter Intr.
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Reference product is powder for inhalation which is different from applied formulation i.e. Rota cap for inhalation..
	Decision of 289th meeting of Registration Board: Registration Board decided to defer the case for further deliberation.	
	Submission by the firm: Firm has submitted following documents:	

	• Evidence of SYMBICORT 100 TURBUHALER (contains 100 mcg of budesonide and 6 mcg of formoterol fumarate dihydrate per dose) approved in Health Canada. • Section approval letter dated 22-12-2020 specifying Dry powder inhaler -New section. • GMP certificate of M/s Werrick Pharmaceuticals issued on the basis of inspection dated 12-08-2022. • DPI device: eziHaler (Trademark number 19748-D) • Delivered dose label claim as: Each delivered dose contains: Budesonide……...…….80mcg Formoterol Fumarate…….4.5mcg	
	Decision: Approved. Registration Board further decided that following label claim for delivered dose shall also be declared on registration letter: **"Each delivered dose contains:** **Budesonide……...…….80mcg** **Formoterol Fumarate…….4.5mcg"**	
999.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.**
	Brand Name +Dosage Form + Strength	BUD-AIR Dry Powder Inhaler 400/6mcg
	Diary No. Date of R& I & fee	Diary No: 15328: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Budesonide…. 400mcg Formoterol fumarate dihydrate….6mcg
	Pharmacological Group	Long acting beta-2-adrenoreceptor agonists/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Canada (MHRA)
	Me-too status	Venticort Rotacaps 100mcg+6mcg Capsule of Macter Int.
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Reference product is powder for inhalation which is different from applied formulation i.e. Rota cap for inhalation.
	Decision of 289th meeting of Registration Board: Registration Board decided to defer the case for further deliberation.	
	Submission by the firm: Firm has submitted following documents: • **Evidence of approval of applied formulation in any RRA is not available** • **Me-too status is not available.** • Section approval letter dated 22-12-2020 specifying Dry powder inhaler -New section. • GMP certificate of M/s Werrick Pharmaceuticals issued on the basis of inspection dated 12-08-2022. • DPI device: eziHaler (Trademark number 19748-D) • Delivered dose label claim as: Each delivered dose contains: Budesonide……...…….320mcg Formoterol Fumarate…….4.5mcg	
	Decision: Approved. Registration Board further decided that following label claim for delivered dose shall also be declared on registration letter: **"Each delivered dose contains:** **Budesonide……...…….320mcg** **Formoterol Fumarate…….4.5mcg**	
1000	Name and address of manufacture / Applicant	M/s Werrick Pahrmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Brand Name + Dosage Form and Strength	Bud-Air Dry Powder Inhalation 400/12mcg capsule

Composition	Each DPI Capsule Contains: Budesonide……400mcg Formoterol fumarate dihydrate……12mcg
Dairy No. date of R &I fee	Form-5 Dy.No 6564 dated 14-02-2019 Rs.20,000/- Dated 14-02-2019
Pharmacological Group	Glucocorticosteroid/Selective β2 adrenoceptor agonist
Type of form	Form 5
Finished product specifications	Manufacturer's specifications
Pack size and Demand Price	30's; As per SRO
Approval status of product in Reference Regulatory Authorities	Symbicort Turbohaler 400micrograms/12micrograms/inhalation, inhalation powder (MHRA approved)
Me-too-status	Formiget DPI Capsule 400mcg+12mcg by Getz Pharma (Reg#098828)
GMP Status	The firm was inspected on 17-01-2019 and conlusion of inspection was: Grant of Section/ Facility and Regularization.

Remark of the Evaluator [XI]

Remarks	**Response by the firm**
• As per 290th decision of Registration board, provide evidence of separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend.	The firm submitted approved layout plan for manufacturing of DPI but have no approved section/manufacturing facility at present. Moreover the firm submitted a list of equipments that will be used in manufacturing including eqipments for DPI mixing, DPI filling, capsule polishing, blistering and packaging. **(No evidence of availability)**
• As per 290th decision of Registration board, provide evidence of equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia.	The firm submitted list of equipments for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" **(No evidence of availability)**
• The reference formulation have mentioned the hydrated form (dihydrate) of Formoterol fumarate in the label claim while you have not mentioned the hydrated form. Revise the label claim as per reference formulation mentioning the hydrated form along with submission of applicable fee.	The firm have revised the label claim mentioning the hydrated form of Formoterol fumarate in the label claim
• Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting.	The firm have submitted commitment for performing the stability study as per Requirements of Registration Board decision of 293rd meeting.

Decision of 296th meeting of Registration Board:
Deferred for confirmation of required manufacturing facility "Dry Powder inhaler" section with manufacturing and testing equiments for applied formulation.

Response by the firm: Firm has submitted following documents:

- Evidence of SYMBICORT FORTE TURBUHALER contains 400 mcg of budesonide and 12 mcg of formoterol fumarate dihydrate per dose approved in Health Canada.
- Section approval letter dated 22-12-2020 specifying Dry powder inhaler -New section.
- GMP certificate of M/s Werrick Pharmaceuticals issued on the basis of inspection dated 12-08-2022.
- DPI device: eziHaler (Trademark number 19748-D)
- Delivered dose label claim as:
  Each delivered dose contains:
  Budesonide……..…….320mcg

	Formoterol Fumarate…….9mcg	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • **Registration Board further decided that following label claim for delivered dose shall also be declared on registration letter:** **"Each delivered dose contains:** **Budesonide……..…….320mcg** **Formoterol Fumarate…….9mcg**	
1001.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.**
	Brand Name +Dosage Form + Strength	IND-AIR Dry Powder Inhaler 150mcg
	Diary No. Date of R& I & fee	Diary No: 15331: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Indacaterol (as maleate)…. 150mcg
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Onbrez Breezhaler 150mcg Inhalation of Novartis Pharma
	GMP status	17-01-2019: Grant of Section/Facility and Regularization.
	Remarks of the Evaluator.	
	Decision of 289th meeting of Registration Board: Registration Board decided to defer the case for further deliberation.	
	Submission by the firm: Firm has submitted following documents: • Evidence of ONBREZ BREEZHALER indacaterol maleate 150 microgram hard capsule for inhalation approved in TGA Australia. • Section approval letter dated 22-12-2020 specifying Dry powder inhaler -New section. • GMP certificate of M/s Werrick Pharmaceuticals issued on the basis of inspection dated 12-08-2022. • DPI device: eziHaler (Trademark number 19748-D) • Delivered dose label claim as: Each delivered dose contains: Indacaterol……120mcg	
	Decision: Approved. Registration Board further decided that following label claim for delivered dose shall also be declared on registration letter: **"Each delivered dose contains:** **Indacaterol……120mcg"**	
1002.	**Name and address of manufacturer / Applicant**	**M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.**
	Brand Name +Dosage Form + Strength	Oxytide-F Dry Powder Inhaler 50/100mcg
	Diary No. Date of R& I & fee	Diary No: 15327: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Salmeterol Xinafoate…. 50mcg Fluticasone propionate….100mcg
	Pharmacological Group	Long acting beta-2-adrenoreceptor agonists/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	28's, 60's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA & TGA
	Me-too status	Seretide Accuhaler 50/100mcg of GSK
	GMP status	As recorded for above application

	Remarks of the Evaluator.	.
	Decision of 289th meeting of Registration Board: Registration Board decided to defer the case for further deliberation.	
	Submission by the firm: Firm has submitted following documents: • Evidence of ADVAIR DISKUS 100/50 (is a purple plastic inhaler containing a foil blister strip. Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) approved in USFDA. • The label claim of the innovator product is different from applied product and is as under: Each blister on the strip contains: Salmeterol (as Xinafoate)…. 50mcg Fluticasone propionate….100mcg • Section approval letter dated 22-12-2020 specifying Dry powder inhaler -New section. • GMP certificate of M/s Werrick Pharmaceuticals issued on the basis of inspection dated 12-08-2022. • DPI device: eziHaler (Trademark number 19748-D) • Delivered dose label claim as: Each delivered dose contains: Salmeterol Xinafoate…. 45mcg Fluticasone propionate….93mcg • The label claim as well as delivered dose of applied product contains salmetrol xinafoate while innovator's product provide label claim and delivered dose for salmetrol base. Firm has not revised its claim or submitted any fee.	
	Decision: Approved. Firm will revise the formulation as per innovator's product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • **Registration Board further decided that following label claim for delivered dose shall also be declared on registration letter:** **"Each delivered dose contains:** **Salmeterol Xinafoate…. 45mcg** **Fluticasone propionate….93mcg"**	
1003	**Name and address of manufacturer / Applicant**	M/s Mafins Pharma A-5 S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Dofin P 50mg Tablet
	Composition	Each sugar coated tablet contains: Diclofenac potassium …50 mg
	Diary No. Date of R& I & fee	Dy.No.823, 9-01-2017, Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diclofenac potassium 50 mg of Accord (MHRA)
	Me-too status	Zumaflam P of zumars Pharma
	GMP status	Last GMP Inspection dated 5-10-17 with conclusive remarks of good cGMP compliance.
	Remarks of Evaluator	Revision of coating without fee
	Decision of 282nd meeting of Registration Board: Deferred for fee for the change of formulation, from enteric, film coated to sugar coated.	
	Response by the firm: Firm has submitted fee PKR 30,000 vide slip number 6769329949 dated 31-10-2022 for revision of formulation.	
	Decision: Approved.	

1004	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals Plot No. 224, Sector 23. Korangi Industrial Area, Karachi.**

	Brand Name +Dosage Form + Strength	Spasfree plus 10/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Hyoscine Butylbromide…10mg Paracetamol…500mg
	Diary No. Date of R& I & fee	Dy No. 15190: 07-03-2019 (ORIGINAL APPLICATION) Dy No. 26333: 19-09-2022 (DUPLICATE DOSSIER) PKR 20,000/-: 06-03-2019
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Buscopan plus tablet by Martin Dow
	GMP status	GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
	Decision of 321st meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Response by the firm: Firm has submitted reference of following RRA approved product: **Name:** Buscopan Plus **Marketing Authorization Holder Name:** CC Pharma GmbH Composition: butylscopolaminium bromide 10mg / paracetamol 500mg film coated tablet **RRA:** Germany Approved	
	Decision: Approved with Innovator's Specifications.	

Case No. 05 Deferred cases of cephradine containing formulations.

Registration Board in its 320th meeting considered the case of "*Review of Reference status of Cephradine for Injection"* and decided as under:

Registration Board deliberated the matter in detail and acknowlwdged the fact that the "Cephradien injection" has not been withdrawan from US market due to safety & efficacy reasons as evident from the above cited notice published in US Federal Register. Hence, Registration Board decided to consider pending registration applications in the light of aforementioned position.

Accordingly, the label claim and specifications of the innovator's product and USP monograph have been reviewed and based upon the label claim of "Velosef Injection 250mg", "Velosef 500mg Injection" & "Velosef injection 1gm" registered vide registration no. 001870, 001866 & 001869 respectively, advised the PE&R division to issue registration letters as per following label claim for generic products.

Each vial contains:
Cephradine ……. 250mg
(with L-arginine)

Each vial contains:
Cephradine ……. 500mg
(with L-arginine)

Each vial contains:
Cephradine ……. 1g
(with L-arginine)

1005	Name and address of manufacturer / Applicant	**M/s Jawa Pharmaceuticals, (Pvt) Ltd. Quiad-e-Azam Industrial area, Lot Lakhpat, Lahore**

	Brand Name +Dosage Form + Strength	Darphin Injection 1gm
	Composition	Each vial contains: Cephradine……...…..1gm
	Diary No. Date of R& I & fee	19-10-2015 diary #1475 Rs.20000
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Velosef Injection 1gm by M/s Apothecon USFDA
	Me-too status	Cefrinex Injection 1gm by M/s Bosch (Reg#015129)
	GMP status	
	Previous remarks of the Evaluator.	Deferred for confirmation of approval status in reference regulatory authorities. Moreover, product has been discontinued by USFDA.
	Previous Decision	Deferred for confirmation of approval status in reference regulatory authorities. Moreover, product has been discontinued by USFDA (M-257).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1006	Name and address of manufacturer / Applicant	**M/s Jawa Pharmaceuticals, (Pvt) Ltd. Quiad-e-Azam Industrial area, Lot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Darphin Injection 500mg
	Composition	Each vial contains:- Cephradine…..….. 500mg
	Diary No. Date of R& I & fee	19-10-2015 diary #1436 Rs.20000
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FDA Velosef Injection 500mg by M/s Apothecon
	Me-too status	Cefrinex Injection 1gm by M/s Bosch (Reg#015129)
	GMP status	
	Previous remarks of the Evaluator.	Deferred for confirmation of approval status in reference regulatory authorities. Moreover, product has been discontinued by USFDA.
	Previous Decision	Deferred for confirmation of approval status in reference regulatory authorities. Moreover, product has been discontinued by USFDA. (M-257).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1007	Name and address of manufacturer / Applicant	M/s. News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	New-Ceph Injection 250 mg IV
	Composition	Each vial contains:- Cephradine with L- Arginine eq. to Cephradine 250 mg
	Diary No. Date of R& I & fee	19-10-2015 diary #1436 Rs.20000
	Pharmacological Group	1st Generation Cephalosporin

	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	Per pack → Rs. Rs. 200/-
	Approval status of product in Reference Regulatory Authorities	USFDA Velosef – Bristol
	Me-too status	Velosef - Bristol
	GMP status	
	Previous remarks of the Evaluator.	Veloef Injection 500mg by M/s GSK
	Previous Decision	
	Evaluation by PEC	Deferred for confirmation of approval status by reference regulatory authorities. (M-261).
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1008	Name and address of manufacturer / Applicant	M/s. News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	New-Ceph Injection 500mg IV
	Composition	Each vial contains:- Cephradine with L- Arginine eq. to Cephradine 500 mg
	Diary No. Date of R& I & fee	Dy # 2480, Rs. 20,000/- 09-06-2016
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	Per pack → Rs. Rs. 360/-
	Approval status of product in Reference Regulatory Authorities	USFDA Velosef – Bristol
	Me-too status	Velosef - Bristol
	GMP status	
	Previous remarks of the Evaluator.	
	Previous Decision	Deferred for confirmation of approval status by reference regulatory authorities. (M-261).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1009	Name and address of manufacturer / Applicant	M/s. News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	New-Ceph Injection 1 GM IV
	Composition	Each vial contains:- Cephradine with L- Arginine eq. to Cephradine…1gm
	Diary No. Date of R& I & fee	Dy # 2479, Rs. 20,000/-,09-06-2016
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	Per pack → Rs. R/7777s. 650/-
	Approval status of product in Reference Regulatory Authorities	USFDA Velosef – Bristol
	Me-too status	Velosef - Bristol
	GMP status	

	Previous remarks of the Evaluator.	
	Previous Decision	Deferred for confirmation of approval status by reference regulatory authorities. (M-261).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1010	Name and address of manufacturer / Applicant	M/s Semos Pharmacuticals (Pvt.) plot 11, sector 12-A, North karachi industrial area Karachi
	Brand Name +Dosage Form + Strength	Semodin Dry Powder Injection
	Composition	Each vial Contains: Cephradine…250mg L-Ariginine….185mg
	Diary No. Date of R& I & fee	Dy.No.1543, Rs.20000/-, 03-08-2016
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	Cost per vial of 250mg Rs. 38.87/-
	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	Velosef BY Glaxo SmithKline Pakistan.
	GMP status	GMP status as depicted in latest inspection report (dated 27-9-14) is Good
	Previous remarks of the Evaluator.	Already considered products include 5 products related to capsule cephalosporins, 7 cephalosporin suspension section and 9 sterile dry powder vial injections in (M-247&M-259). Now the firm has applied for 2 capsule cephalosporin, 2 cephalosporin suspension and 1 sterile powder vial for injection.
	Previous Decision	Deferred for confirmation of approval status by reference regulatory authorities. (M-262).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1011	Name and address of manufacturer / Applicant	M/s.Medisave Pharma Lahore
	Brand Name +Dosage Form + Strength	Piocef Injection 500mg Broad-spectrum antibiotic
	Composition	Each vial contains:- Cephradine with L-Arginine equilvalent to cephradine
	Diary No. Date of R& I & fee	4-6-2012, Dy No.332, 8000/- &12000/-
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specs
	Pack size & Demanded Price	1's ,As per SRO
	Approval status of product in Reference Regulatory Authorities	VELOSEF by APOTHECON, USFDA approved
	Me-too status	Cefatil by Highnoon
	GMP status	Last inspection, 09-05-2016, GMP is satisfactory
	Previous remarks of the Evaluator.	

	Previous Decision	Deferred for confirmation of approval by reference regulatory authorities. Board further directed to confirm the reasons of Discontinued status of applied formulation in USFDA (M-264)
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1012	Name and address of manufacturer / Applicant	M/s. Medisave Pharma Lahore
	Brand Name +Dosage Form + Strength	Piocef Injection 1gm
	Composition	Each vial contains:- Cephradine with L-Arginine eq.to cephradine USP….1gm
	Diary No. Date of R& I & fee	4-6-2012, Dy no. 352, 8000 &12000/-19-11-2014
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specs
	Pack size & Demanded Price	1's ,As per SRO
	Approval status of product in Reference Regulatory Authorities	VELOSEF by APOTHECON, USFDA approved
	Me-too status	Cefatil by Highnoon
	GMP status	Last inspection, 09-05-2016, GMP is satisfactory
	Previous remarks of the Evaluator.	
	Previous Decision	Deferred for confirmation of approval by reference regulatory authorities. Board further directed to confirm the reasons of Discontinued status of applied formulation in USFDA (M-264)
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1013	Name and address of manufacturer / Applicant	**M/s. MTI Medical (Pvt) Ltd.** 586-587 Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	**Dynarid Injection 1gm**
	Composition	Each Vial contains: Cephradine wih l-arginine …1gm
	Diary No. Date of R& I & fee	Diary No: 3453, 17/04/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's Vial with WFI 2x5ml / As per SRO
	Approval status of product in Reference Regulatory Authorities	Velosef Injection 1gm by M/s Apothecon USFDA (**disconinued**)
	Me-too status	Cefrinex Injection 1gm by M/s Bosch (Reg#015129)
	GMP status	**22-11-16** Grant of new section Grant of Additional section Recommended
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.

		• Source of WFI (Medistil 5ml) by M/s Medisave Pharmaceuticals (Reg#064758)
	Previous Decision	Deferred for evidence of approval of applied formulation by reference regulatory authorities (M-270).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1014	Name and address of manufacturer / Applicant	**M/s. MTI Medical (Pvt) Ltd.** 586-587 Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	**Dynarid Injection 500mg**
	Composition	Each Vial contains: Cephradine wih l-arginine …500mg
	Diary No. Date of R& I & fee	Diary No: 3440, 17/04/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's Vial with WFI 5ml / As per SRO
	Approval status of product in Reference Regulatory Authorities	Velosef Injection 500mg by M/s Apothecon USFDA (**disconinued**)
	Me-too status	Cefrinex Injection 500mg by M/s Bosch (Reg#015128)
	GMP status	**22-11-16** Grant of new section Grant of Additional section Recommended
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed. • Source of WFI (Medistil 5ml) by M/s Medisave Pharmaceuticals (Reg#064758)
	Previous Decision	Deferred for evidence of approval of applied formulation by reference regulatory authorities (M-270).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1015	Name and address of manufacturer / Applicant	**M/s Pak-Heim International Pharma, Lahore contract manufactured by Friends pharma, Lahore**
	Brand Name +Dosage Form + Strength	Cefheim Dry powder for Injection 250mg
	Composition	Each vial contains: Cephradine (with l-Arginine)USP…….250mg
	Diary No. Date of R& I & fee	2779, 16-8-2010, Rs 8000, Rs 42,000
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's vial, As per SRO
	Approval status of product in Reference Regulatory Authorities	**USFDA (Discontinued)**
	Me-too status	Velosef by GSK
	GMP status	Last inspection report (Friends Pharma) 6-10-2016. The panel grant the cGMP for export purpose.

	Previous remarks of the Evaluator.	• No.F.8-6/2013-Reg-V Pakheim's 8 numbers of files has been send to PEC for evaluation. No registration has been issued of contract to M/S Pakheim Pharmaceutical, Lahore. • Pakheim has following sections according to letter No.F.1-16/99-Lic(vol-II). A) General Dry Syrup B) General Sachet Section C) Ceph Dry Syrup. • Friends Pharma has Injection (Dry powder Cephalosporin) Section
	Previous Decision	Deferred for confirmation of approval status of formulation in reference regulatory authorities. (M-270).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1016	Name and address of manufacturer / Applicant	**M/s Pak-Heim International Pharma, Lahore contract manufactured by Friends pharma, Lahore**
	Brand Name +Dosage Form + Strength	Cefheim Dry powder for Injection 500mg
	Composition	Each vial contains: Cephradine (with L-Arginine) USP….500mg
	Diary No. Date of R& I & fee	7458, 9-8-2010, Rs 8000, Rs 42000
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's vial, As per SRO
	Approval status of product in Reference Regulatory Authorities	**USFDA (Discontinued)**
	Me-too status	Velosef by GSK
	GMP status	Last inspection report (Friends Pharma) 6-10-2016. The panel grant the cGMP for export purpose.
	Previous remarks of the Evaluator.	• No.F.8-6/2013-Reg-V Pakheim's 8 numbers of files has been send to PEC for evaluation. No registration has been issued of contract to M/S Pakheim Pharmaceutical, Lahore. • Pakheim has following sections according to letter No.F.1-16/99-Lic(vol-II). A) General Dry Syrup B) General Sachet Section C) Ceph Dry Syrup. • Friends Pharma has Injection (Dry powder Cephalosporin) Section
	Previous Decision	Deferred for confirmation of approval status of formulation in reference regulatory authorities (M-270).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1017	Name and address of manufacturer / Applicant	**M/s Pak-Heim International Pharma, Lahore contract manufactured by Friends pharma, Lahore**
	Brand Name +Dosage Form + Strength	Cefheim Dry powder for Injection 1000mg
	Composition	Each vial contains: Cephradine (with l-Arginine) USP….1000mg
	Diary No. Date of R& I & fee	7459, 9-8-2010, Rs 8000, Rs 42000

	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's vial, As per SRO
	Approval status of product in Reference Regulatory Authorities	**USFDA (Discontinued)**
	Me-too status	Velosef by GSK
	GMP status	Last inspection report (Friends Pharma) 6-10-2016. The panel grant the cGMP for export purpose.
	Previous remarks of the Evaluator.	• No.F.8-6/2013-Reg-V Pakheim's 8 numbers of files has been send to PEC for evaluation. No registration has been issued of contract to M/S Pakheim Pharmaceutical, Lahore. • Pakheim has following sections according to letter No.F.1-16/99-Lic(vol-II). A) General Dry Syrup B) General Sachet Section C) Ceph Dry Syrup. • Friends Pharma has Injection (Dry powder Cephalosporin) Section
	Previous Decision	Deferred for confirmation of approval status of formulation in reference regulatory authorities (M-270).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1018	Name and address of manufacturer / Applicant	M/s. Sharex Laboratories (Pvt) Ltd., K.L.P. Road Sadiqabad
	Brand Name +Dosage Form + Strength	F.radine Injection 250 mg IM/IV
	Composition	Each vial contains Cephradine …….. 250mg
	Diary No. Date of R& I & fee	Dy. No. 3318 : 21-12-2016 PKR 20,000/- : 20-12-2016
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's : Rs 48/
	Approval status of product in Reference Regulatory Authorities	USFDA approved but discontinued
	Me-too status	Cefrinex by Bosch
	GMP status	Last inspection report dated 11-05-2016 recommended renewal of DML and grant of additional sections
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed • Firm has claimed shelf life of 3 years and stability data sheet of only 1 batch which was manufactured on 08-06-2013 and expired on 08-06-2016
	Previous Decision	**Registration Board deferred all the applications pertaining to the cephalosporin dry powder injection section for clarification since stability studies submitted by the firm shows manufacturing of applied drugs before approval of section by the Central Licensing Board.** (M-271).
	Evaluation by PEC	
	Decision: Approved with USP Specifications.	

	Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1019	Name and address of manufacturer / Applicant	M/s. Sharex Laboratories (Pvt) Ltd., K.L.P. Road Sadiqabad
	Brand Name +Dosage Form + Strength	F.radine Injection 500 mg IM/IV
	Composition	Each vial contains Cephradine……. 500 mg
	Diary No. Date of R& I & fee	Dy. No. 3319 : 21-12-2016 PKR 20,000/- : 20-12-2016
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's : Rs 60/
	Approval status of product in Reference Regulatory Authorities	• USFDA approved but discontinued ANSM France approved as IV only but archived on 07-05-2011
	Me-too status	Cefrinex by Bosch
	GMP status	Last inspection report dated 11-05-2016 recommended renewal of DML and grant of additional sections
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed • Firm has claimed shelf life of 3 years and stability data sheet of only 1 batch which was manufactured on 08-06-2013 and expired on 08-06-2016
	Previous Decision	**Registration Board deferred all the applications pertaining to the cephalosporin dry powder injection section for clarification since stability studies submitted by the firm shows manufacturing of applied drugs before approval of section by the Central Licensing Board.** (M-271).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1020	Name and address of manufacturer / Applicant	M/s. Sharex Laboratories (Pvt) Ltd., K.L.P. Road Sadiqabad
	Brand Name +Dosage Form + Strength	F.radine Injection 1 gm IM/IV
	Composition	Each vial contains Cephradine ……..1g
	Diary No. Date of R& I & fee	Dy. No. 3320 : 21-12-2016 PKR 20,000/- : 20-12-2016
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's : Rs 103/
	Approval status of product in Reference Regulatory Authorities	• USFDA approved but discontinued ANSM France approved as IV only but archived on 07-05-2011
	Me-too status	Cefrinex by Bosch
	GMP status	Last inspection report dated 11-05-2016 recommended renewal of DML and grant of additional sections

	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed • Firm has claimed shelf life of 3 years and stability data sheet of only 1 batch which was manufactured on 08-06-2013 and expired on 08-06-2016
	Previous Decision	**Registration Board deferred all the applications pertaining to the cephalosporin dry powder injection section for clarification since stability studies submitted by the firm shows manufacturing of applied drugs before approval of section by the Central Licensing Board.** (M-271).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1021	Name and address of manufacturer / Applicant	M/s City Pharmaceuticals, Plot No. 12A, 15 New Servey No-276, Sector 5, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Roxocef 500mg Injection
	Composition	Each vial contains: Cephradine…….500 mg
	Diary No. Date of R& I & fee	Dy No. 1079: 26-5-2016PKR 20,000/-: 25-5-2016
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	• USFDA approved but discontinued. • ANSM France approved as IV only but archived on 07-05-2011.
	Me-too status	Cefrinex by Bosch
	GMP status	Last inspection report dated 10-4-2017 confirms good compliance to GMP
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed
	Previous Decision	**Deferred for evidence of approval in reference regulatory authorities** .(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1022	Name and address of manufacturer / Applicant	M/s City Pharmaceuticals, Plot No. 12A, 15 New Servey No-276, Sector 5, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Roxocef 1000mg Injection
	Composition	Each vial contains: Cephradine…….1000 mg
	Diary No. Date of R& I & fee	Dy No. 1081: 26-5-2016PKR 20,000/-: 25-5-2016
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC

	Approval status of product in Reference Regulatory Authorities	• USFDA approved but discontinued. • ANSM France approved as IV only but archived on 07-05-2011.
	Me-too status	Cefrinex by Bosch
	GMP status	Last inspection report dated 10-4-2017 confirms good compliance to GMP
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed
	Previous Decision	**Deferred for evidence of approval in reference regulatory authorities** .(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1023	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals, Plot # 11, sector 12-A, Industrial area, North Karachi
	Brand Name +Dosage Form + Strength	Semodin Dry Powder Injection IV/IM
	Composition	Each vial contains: Cephradine……1000 mg (Mixture contains L-Arginine)
	Diary No. Date of R& I & fee	Dy.No. 1541, 3-8-16, Rs.20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	• CEFRADINE PANPHARMA 1 g (ANSAM) status; is Archived (in 2016)
	Me-too status	AKSOSEF of AKSON PHARMACEUTICALS
	GMP status	Last GMP Inspection dated 15-2-17 with conclusive remarks of Good level of cGMP compliance.
	Previous remarks of the Evaluator.	• Presence of L-arginine in formulation in stringent regulatory author can't be verified. • Evidence of international availability can't be confirmed
	Previous Decision	**Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.**.(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1024	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals, Plot # 11, sector 12-A, Industrial area, North Karachi
	Brand Name +Dosage Form + Strength	Semodin 500 mg injection IV/IM
	Composition	Each vial contains: Cephradine……500 mg (Mixture contains L-Arginine)
	Diary No. Date of R& I & fee	Dy.No. 1544, 3-8-16, Rs.20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	• CEFRADINE PANPHARMA (IV) 500 mg powder and solvent for solution for injection (ANSAM) but Status is archived (2011)
	Me-too status	AKSOSEF of AKSON PHARMACEUTICALS
	GMP status	Last GMP Inspection dated 15-2-17 with conclusive remarks of Good level of cGMP compliance.
	Previous remarks of the Evaluator.	• Presence of L-arginine in formulation in stringent regulatory author can't be verified. • Evidence of international availability can't be confirmed
	Previous Decision	**Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.**.(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1025	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals, Plot # 11, sector 12-A, Industrial area, North Karachi
	Brand Name +Dosage Form + Strength	Semodin 500 mg injection IV/IM
	Composition	Each vial contains: Cephradine……500 mg (Mixture contains L-Arginine)
	Diary No. Date of R& I & fee	Dy.No. 1544, 3-8-16, Rs.20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	CEFRADINE PANPHARMA (IV) 500 mg powder and solvent for solution for injection (ANSAM) but Status is archived (2011)
	Me-too status	AKSOSEF of AKSON PHARMACEUTICALS
	GMP status	Last GMP Inspection dated 15-2-17 with conclusive remarks of Good level of cGMP compliance.
	Previous remarks of the Evaluator.	• Presence of L-arginine in formulation in stringent regulatory author can't be verified. • Evidence of international availability can't be confirmed
	Previous Decision	**Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.** .(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1026	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi.

	Brand Name +Dosage Form + Strength	Cefbeck Injection(IV/IM) 1g
	Composition	Each vial contains: Sterile Cephradine with (sterile L-Arginine)… 1g
	Diary No. Date of R& I & fee	Dy No.1185; 28-12-2015; Rs.20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; Rs.107.01/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA(discontinued)
	Me-too status	Velosef of GSK.
	GMP status	Last inspection report dated 8-8-2017 confirms satisfactory compliance to GMP.
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies.** .(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1027	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi.
	Brand Name +Dosage Form + Strength	Cefbeck Injection(IV/IM) 500mg
	Composition	Each vial contains: Sterile Cephradine with (sterile L-Arginine)… 500mg
	Diary No. Date of R& I & fee	Dy No.1184; 28-12-2015; Rs.20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; Rs.58.36/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA(discontinued)
	Me-too status	Velosef of GSK.
	GMP status	Last inspection report dated 8-8-2017 confirms satisfactory compliance to GMP.
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies.** .(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1028	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan, F/423, S.I.T.E, Karachi.
	Brand Name +Dosage Form + Strength	Cefbeck Injection(IV/IM) 250mg

	Composition	Each vial contains: Sterile Cephradine with (sterile L-Arginine)… 250mg
	Diary No. Date of R& I & fee	Dy No.1189 ; 28-12-2015; Rs.20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; Rs.44.71/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA(discontinued)
	Me-too status	Velosef of GSK.
	GMP status	Last inspection report dated 8-8-2017 confirms satisfactory compliance to GMP.
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies.** .(M-274).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1029	Name and address of manufacturer / Applicant	M/s Inventor Pharma, Plot No. K/196, S.I.T.E, (SHW) Phase-II, Karachi
	Brand Name +Dosage Form + Strength	Incef 1gm I.V Injection
	Composition	Each vial contains:- Cephradine …1gm (Mixture contains L-Arginine)
	Diary No. Date of R& I & fee	Diary No: 13633, 28/08/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's/ As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA(discontinued)
	Me-too status	Veloadvan 1gm Injection by M/s Advanced Pharmaceuticals (Reg#065372)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed (USFDA discontinued. Archived in ANSM France approved as IV on 07-5-2011.) Presence of L-arginine in formulation in Reference Regulatory Authorities can't be verified.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**(M-277).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration**	

	correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1030	Name and address of manufacturer / Applicant	M/s Inventor Pharma, Plot No. K/196, S.I.T.E, (SHW) Phase-II, Karachi
	Brand Name +Dosage Form + Strength	Incef 500mg I.V Injection
	Composition	Each vial contains:- Cephradine …500mg (Mixture contains L-Arginine)
	Diary No. Date of R& I & fee	Diary No: 13638, 28/08/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's/ As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA(discontinued)
	Me-too status	Veloadvan 500mg Injection by M/s Advanced Pharmaceuticals (Reg#065371)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed (USFDA discontinued.Archived in ANSM France approved as IV on 07-5-2011.). • Presence of L-arginine in formulation in Reference Regulatory Authorities can't be verified.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**(M-277).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1031	Name and address of manufacturer / Applicant	M/s Inventor Pharma, Plot No. K/196, S.I.T.E, (SHW) Phase-II, Karachi
	Brand Name +Dosage Form + Strength	Incef 250mg I.V Injection
	Composition	Each vial contains:- Cephradine …250mg (Mixture contains L-Arginine)
	Diary No. Date of R& I & fee	Diary No: 13638, 28/08/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's/ As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA(discontinued)
	Me-too status	Veloadvan 250mg Injection by M/s Advanced Pharmaceuticals (Reg#065370)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Previous remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed (USFDA discontinued.Archived in ANSM France approved as IV on 07-5-2011.).

		• Presence of L-arginine in formulation in Reference Regulatory Authorities can't be verified.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**.(M-277).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1032	Name and address of manufacturer / Applicant	M/s EG Pharmaceuticals 13-A, industrial triangle, Kahuta road Islamabad.
	Brand Name +Dosage Form + Strength	Selovef 500 mg injection IV
	Composition	Each vial contains:- Cefradine……..500 mg
	Diary No. Date of R& I & fee	Dy.No. 1835, 19-10-16, Rs.20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's / As per PRC
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Aksosef of Akson Pharmaceuticals
	GMP status	Last GMP Inspection dated 22-06-2017 with conclusive remarks of reasonable cGMP compliance
	Previous remarks of the Evaluator.	• CEFRADINE PANPHARMA (IV) 500 mg powder and solvent for solution for injection (ANSAM) but Status is archived (2011)
	Previous Decision	**Registration Board deferred the case for rectification of all the short coming as stated in GMP inspection report. The Board further directed to send a reference to QA & LT Division to conduct GMP inspection of Firm on priority.** (M-277).
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1033	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry(Pvt.) Ltd. A-37, Small Industrial Estate Township Kohat Road Bannu.
	Brand Name +Dosage Form + Strength	TILOCEF-500mg INJECTION (IM/IV)
	Composition	Each vial contains: Cephradine with L-Arginine….500mg
	Diary No. Date of R& I & fee	Diary No: 26598, 29/12/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's /As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued ANSM France approved as IV only but archived on 07.05.2011
	Me-too status	Linadine 500mg Injection by M/s Alina (Reg#070736)
	GMP status	05/10/2017

		Grant of renewal of DML and additional sections. Panel recommends DML renewal and additional sections
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed. • Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities. • Firm has not submitted master formulation of applied product.
	Previous Decision	**Deferred for following:** • **Evidence of approval of applied formulation with active status of market in reference regulatory authorities could not be confirmed.** • **Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities.** **Master formulation of applied product. (M-278)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1034	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry(Pvt.) Ltd. A-37, Small Industrial Estate Township Kohat Road Bannu.
	Brand Name +Dosage Form + Strength	TILOCEF-250mgINJECTION (IM/IV)
	Composition	Each vial contains: Cephradine with L-Arginine….250mg
	Diary No. Date of R& I & fee	Diary No: 26597, 29/12/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's /As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued
	Me-too status	Fostrum 250mg Injection by M/s Pulse Pharmaceuticals (Reg#074171)
	GMP status	05/10/2017 Grant of renewal of DML and additional sections. Panel recommends DML renewal and additional sections
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed. • Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities. • Firm has not submitted master formulation of applied product.
	Previous Decision	**: Deferred for following:** • **Evidence of approval of applied formulation with active status of market in reference regulatory authorities could not be confirmed.** • **Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities.** **Master formulation of applied product. (M-278)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications.	

	Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1035	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry(Pvt.) Ltd. A-37, Small Industrial Estate Township Kohat Road Bannu.
	Brand Name +Dosage Form + Strength	TILOCEF-1 g INJECTION(IM/IV)
	Composition	Each vial contains: Cephradine with L-Arginine….1000mg
	Diary No. Date of R& I & fee	Diary No: 26599, 29/12/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's /As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued ANSM France approved separately as IV and IM but archived on 26-04-2016
	Me-too status	Fostrum 1g Injection by M/s Pulse Pharmaceuticals (Reg#074172)
	GMP status	05/10/2017 Grant of renewal of DML and additional sections. Panel recommends DML renewal and additional sections
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed. • Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities. • Firm has not submitted master formulation of applied product.
	Previous Decision	**Deferred for following:** • **Evidence of approval of applied formulation with active status of market in reference regulatory authorities could not be confirmed.** • **Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities.** **Master formulation of applied product. (M-278)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1036	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry(Pvt.) Ltd. A-37, Small Industrial Estate Township Kohat Road Bannu.
	Brand Name +Dosage Form + Strength	TILOCEF-1 g INJECTION(IM/IV)
	Composition	Each vial contains: Cephradine with L-Arginine….1000mg
	Diary No. Date of R& I & fee	Diary No: 26599, 29/12/2017, Rs: 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's /As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued ANSM France approved separately as IV and IM but archived on 26-04-2016

	Me-too status	Fostrum 1g Injection by M/s Pulse Pharmaceuticals (Reg#074172)
	GMP status	05/10/2017 Grant of renewal of DML and additional sections. Panel recommends DML renewal and additional sections
	Previous remarks of the Evaluator.	• Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed. • Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities. • Firm has not submitted master formulation of applied product.
	Previous Decision	**Deferred for following:** • **Evidence of approval of applied formulation with active status of market in reference regulatory authorities could not be confirmed.** • **Evidence of L-Arginine in formulation not confirmed in Reference Regulatory Authorities.** **Master formulation of applied product. (M-278)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1037	Name and address of manufacturer / Applicant	M/s. Friends Pharma, 31 km, Ferozepur road Lahore
	Brand Name +Dosage Form + Strength	Viocef injection 250 mg
	Composition	Each glass vial contains: Cephradine HCl…… 250 mg
	Diary No. Date of R& I & fee	Dy. No.508; 9-1-2017; Rs. 20,000/-
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved but discontinued
	Me-too status	Cefrinex by Bosch
	GMP status	Last GMP Inspection dated 6 oct 2016 with conclusive remarks of cGMP compliance.
	Previous remarks of the Evaluator.	• Latest GMP inspection report (which should have been conducted within the period of last one year). • Evidence of approval of applied formulation in reference regulatory authorities could not be confirmed
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting and updated status of GMP of the firm form QA & LT division as inspection report submitted by firm is not with in one year.** **(M-281)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications.	

	Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1038	Name and address of manufacturer / Applicant	M/s Getz Pharma Karachi, ***contract manufacturing*** from M/s Novamed Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Lenwin powder for injection 250mg
	Composition	Each vial contains: Cephradine monohydrate eq to cephradine…..250mg
	Diary No. Date of R& I & fee	Dy. No.4339; 3-01-2017; Rs.50,000/- (30-12-2016)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's, Rs.150/-
	Approval status of product in Reference Regulatory Authorities	USFDA approved but discontinued
	Me-too status	Cefrinex by Bosch
	GMP status	Last inspection report (Novomed Pharmaceuticals) 5th and 27th December 2017,firm is compliant to Good cGMP guideline at the time of inspection.
	Previous remarks of the Evaluator.	• Firm has cephalosporin injectable section
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting (M-282)**
	Evaluation by PEC	Capacity assessment inspection report of M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore presented in 295th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections: • Dry Powder Injection (Cephalosporin) Section • Dry Powder Suspension (Cephalosporin) Section • Capsule (Cephalosporin) Section • General Liquid Injection (Ampoule) General Liquid Injection Vials (SVP)
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals, Lahore.**	
1039	Name and address of manufacturer / Applicant	M/s Getz Pharma Karachi, ***contract manufacturing*** from M/s Novamed Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Lenwin powder for injection 500mg
	Composition	Each vial contains: Cephradine monohydrate eq to cephradine…..500mg
	Diary No. Date of R& I & fee	Dy. No.4338; 3-01-2017; Rs.50,000/- (30-12-2016)
	Pharmacological Group	1st Gen Cephalosporin

	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's, Rs.150/-
	Approval status of product in Reference Regulatory Authorities	VELOSEF 500mg Injection by M/s APOTHECON (USFDA Discontinued)
	Me-too status	V-Sef Injection 500mg by M/s Z-JANS Pharmaceuticals (Reg#024068)
	GMP status	Last inspection report (Novomed Pharmaceuticals) 5th and 27th December 2017,firm is compliant to Good cGMP guideline at the time of inspection.
	Previous remarks of the Evaluator.	Firm has cephalosporin injectable section.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting (M-282)**
	Evaluation by PEC	Capacity assessment inspection report of M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore presented in 295th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections: • Dry Powder Injection (Cephalosporin) Section • Dry Powder Suspension (Cephalosporin) Section • Capsule (Cephalosporin) Section • General Liquid Injection (Ampoule) General Liquid Injection Vials (SVP)
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals, Lahore.**	
1040	Name and address of manufacturer / Applicant	M/s Getz Pharma Karachi, ***contract manufacturing*** from M/s Novamed Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Lenwin powder for injection 1gm
	Composition	Each vial contains: Cephradine monohydrate eq to cephradine…..1gm
	Diary No. Date of R& I & fee	Dy. No.4337; 3-01-2017; Rs.50,000/- (30-12-2016)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's, Rs.200/-
	Approval status of product in Reference Regulatory Authorities	VELOSEF 1000mg Injection by M/s APOTHECON (USFDA Discontinued)
	Me-too status	V-Sef Injection 1000mg by M/s Z-JANS Pharmaceuticals (Reg#024069)
	GMP status	Last inspection report (Novomed Pharmaceuticals) 5th and 27th December 2017,firm is compliant to Good cGMP guideline at the time of inspection.
	Previous remarks of the Evaluator.	Firm has cephalosporin injectable section.

	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. (M-282)**
	Evaluation by PEC	Capacity assessment inspection report of M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore presented in 295th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections: • Dry Powder Injection (Cephalosporin) Section • Dry Powder Suspension (Cephalosporin) Section • Capsule (Cephalosporin) Section • General Liquid Injection (Ampoule) General Liquid Injection Vials (SVP)
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals, Lahore.**	
1041	Name and address of manufacturer / Applicant	M/S High –Q Pharmaceuticals, Plot No ; 224/23 Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Cefrinex 250mg Injection (IV,IM)
	Composition	Each vial contains: Cephradine (as Dihydrate) with L-Arginine ……250mg
	Diary No. Date of R& I & fee	Dy.No.18912;24-10-2017; Rs.20,000/- (23-10-2017)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued ANSM France approved as IV only but archived on 07.05.2011
	Me-too status	Welphardine 250mg Injection M/s WelMark Pharmaceutical,
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. (M-284)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications.	

	Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1042	Name and address of manufacturer / Applicant	M/S High –Q Pharmaceuticals, Plot No ; 224/23 Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Cefrinex 500mg Injection (IV,IM)
	Composition	Each vial contains: Cephradine (as Dihydrate) with L-Arginine ……500mg
	Diary No. Date of R& I & fee	Dy.No.18913; 24-10-2017; Rs.20,000/- (23-10-2017))
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued. ANSM France approved as IV only but archived on 07.05.2011
	Me-too status	Veloadvan 500mg Injection M/s AdvancedPharmaceuticals,
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. (M-284)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1043	Name and address of manufacturer / Applicant	M/s Standpharm (Pvt.) limited, 20 Km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Cephdine injection 250mg
	Composition	Each vial contains: Cephradine ……..250mg
	Diary No. Date of R& I & fee	Dy.No.17180; 05-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Not provided
	Pack size & Demanded Price	1's vial + solvent (WFI 5ML ampoule) & Rs.66/-per vial
	Approval status of product in Reference Regulatory Authorities	Discontinued in USFDA
	Me-too status	Velosef injection 250mg of M/s Squibb (Reg. # 001870)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes: "The detailed inspection was conducted for the verification of current GMP compliance. It was notated that the firm had segregated the Cephalosporin manufacturing facility, however, it was not truly dedicated. The firm was advised to provide dedicated facility for manufacturing of Cephalosporin products. The overall facilities were found to be operating at

		satisfactory level of GMP compliance at the time of inspection. The firm had sufficient qualified/ technical staff and given the commitment for re-vamping as a continuous improvement activity.
	Previous remarks of the Evaluator.	• The official monograph of the applied formulation is available in BP. • The evidence of applied formulation in the reference regulatory authorities could not be confirmed. • Dedicated manufacturing facility for Cephalosporin products in the applicant's firm could not be confirmed.
	Previous Decision	**Deferred for following:** • **Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.** • **Dedicated manufacturing facility for Cephalosporin products. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1044	Name and address of manufacturer / Applicant	M/s Standpharm (Pvt.) limited, 20 Km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Cephdine injection 500mg
	Composition	Each vial contains: Cephradine ……..500mg
	Diary No. Date of R& I & fee	Dy.No.17181; 05-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Not provided
	Pack size & Demanded Price	1's vial + solvent (WFI 5ML ampoule) & Rs.66/-per vial
	Approval status of product in Reference Regulatory Authorities	Discontinued in USFDA
	Me-too status	Velosef injection 250mg of M/s Squibb (Reg. # 001870)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes: "The detailed inspection was conducted for the verification of current GMP compliance. It was notated that the firm had segregated the Cephalosporin manufacturing facility, however, it was not truly dedicated. The firm was advised to provide dedicated facility for manufacturing of Cephalosporin products. The overall facilities were found to be operating at satisfactory level of GMP compliance at the time of inspection. The firm had sufficient qualified/ technical staff and given the commitment for re-vamping as a continuous improvement activity.
	Previous remarks of the Evaluator.	• The official monograph of the applied formulation is available in BP. • The evidence of applied formulation in the reference regulatory authorities could not be confirmed. • Dedicated manufacturing facility for Cephalosporin products in the applicant's firm could not be confirmed.

	Previous Decision	**Deferred for following:** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Dedicated manufacturing facility for Cephalosporin products. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1045	Name and address of manufacturer / Applicant	M/s Standpharm (Pvt.) limited, 20 Km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Cephdine injection 1g
	Composition	Each vial contains: Cephradine….1g
	Diary No. Date of R& I & fee	Dy.No.17182; 05-10-2017; Rs.20,000/- (04-10-2017)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Not provided
	Pack size & Demanded Price	1's vial + solvent (w.f.i.10ml ampoule) & Rs. 160/vial
	Approval status of product in Reference Regulatory Authorities	Discontinued in USFDA
	Me-too status	Cephradine 1g Injection of M/s Highnoon (Reg.# 009140)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes: "The detailed inspection was conducted for the verification of current GMP compliance. It was notated that the firm had segregated the Cephalosporin manufacturing facility, however, it was not truly dedicated. The firm was advised to provide dedicated facility for manufacturing of Cephalosporin products. The overall facilities were found to be operating at satisfactory level of GMP compliance at the time of inspection. The firm had sufficient qualified/ technical staff and given the commitment for re-vamping as a continuous improvement activity.
	Previous remarks of the Evaluator.	• The official monograph of the applied formulation is available in BP. • The evidence of applied formulation in the reference regulatory authorities could not be confirmed. • Dedicated manufacturing facility for Cephalosporin products in the applicant's firm could not be confirmed.
	Previous Decision	**Deferred for following:** • **Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.** • **Dedicated manufacturing facility for Cephalosporin products. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications.	

	Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1046	Name and address of manufacturer / Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Hidin injection 250mg
	Composition	Each vial contains: Cephradine with L- Arginine eq. to Cephradine…..250mg
	Diary No. Date of R& I & fee	Dy. No. 7686; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturers
	Pack size & Demanded Price	1's vial + solvent (w.f.i.10ml ampoule) & Rs. 160/vial
	Approval status of product in Reference Regulatory Authorities	1x 1 vial & Rs. 44/- or as per SRO
	Me-too status	Discontinued in USFDA
	GMP status	Velosef injection 250mg of M/s Squibb (Reg. # 001870)
	Previous remarks of the Evaluator.	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous Decision	**Deferred for following reasons:** • **Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Justification of the applied 5% overage. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1047	Name and address of manufacturer / Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Hidin injection 500mg
	Composition	Each vial contains: Cephradine with L- Arginine eq. to Cephradine…..500mg
	Diary No. Date of R& I & fee	Dy. No. 7687; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturers
	Pack size & Demanded Price	500mg x 1's vial & Rs. 58/- or as per SRO
	Approval status of product in Reference Regulatory Authorities	Discontinued in USFDA
	Me-too status	Velosef injection 500mg of M/s Squibb (Reg. # 001866)

	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous remarks of the Evaluator.	• International availability of the applied formulation could not be confirmed. • 5% overage is applied. • The official monograph of the applied formulation is available in BP. • Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous Decision	**Deferred for following reasons:** • **Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** • **Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Justification of the applied 5% overage. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1048	Name and address of manufacturer / Applicant	M/s Himedic Pharmaceutical (Pvt.) Limited, 19-km Link Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Hidin injection 1g
	Composition	Each vial contains: Cephradine with L- Arginine eq. to Cephradine…..1g
	Diary No. Date of R& I & fee	Dy. No. 7689; 06-07-2017; Rs.20,000/-(06-07-2017)
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	Manufacturers
	Pack size & Demanded Price	1g x 1's vial & Rs. 107/- or as per SRO
	Approval status of product in Reference Regulatory Authorities	Discontinued in USFDA
	Me-too status	Velosef injection 1g of M/s Squibb (Reg. # 001869)
	GMP status	Last GMP inspection was conducted on 09-08-2018 and the report concludes satisfactory compliance with following remarks: "Firm was advised to submit an action plan for rectifications for further improvement of GMP compliance of the firm."
	Previous remarks of the Evaluator.	• International availability of the applied formulation could not be confirmed. • 5% overage is applied. • The official monograph of the applied formulation is available in BP.

		• Firm was issued letter on 29-05-2018 and reminder on 17-08-2018 but the firm has replied on 12-09-2018 which is incorrect.
	Previous Decision	**Deferred for following reasons:** • **Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Justification of the applied 5% overage. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1049	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Cefradin IV/IM Injection 250mg.
	Composition	Each vial contains: Cephradine L-Arginine Eq. to Cephradine …….250mg.
	Diary No. Date of R& I & fee	Dy. No 9612 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Velosef Injection by GSK-Pakistan
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting
	Previous Decision	• **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting.. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1050	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Cefradin IV/IM Injection 500mg.
	Composition	Each vial contains: Cephradine L-Arginine Eq. to Cephradine …….500mg.

	Diary No. Date of R& I & fee	Dy. No 9613 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefril-A Injection Bristol-Myers Squibb
	Me-too status	Velosef Injection by GSK-Pakistan
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting
	Previous Decision	• **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1051	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Cefradin IV/IM Injection 1000mg
	Composition	Each vial contains: Cephradine L-Arginine Eq. to Cephradine …….1000mg.
	Diary No. Date of R& I & fee	Dy. No 9614 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefril-A Injection Bristol-Myers Squibb
	Me-too status	Velosef Injection by GSK-Pakistan
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting
	Previous Decision	• **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting. (M-285)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	

1052	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Volvocef 250mg Injection
	Composition	Each vial contains: Cephradine with Sterile Arginine eq. to Cephradine.....250mg
	Diary No. Date of R& I & fee	Dy. No. 8715 dated 27/07/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	1‘s:
	Approval status of product in Reference Regulatory Authorities	Cannot be confirmed
	Me-too status	Velosef 250mg Injection Reg: No. 001870 Bristol Myer Squib Pakistan/GSK.
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Previous Decision	• **Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-291)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1053	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Volvocef 500mg Injection
	Composition	Each vial contains: Cephradine with Sterile Arginine eq. to Cephradine.....500mg
	Diary No. Date of R& I & fee	Dy. No. 8716 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	1‘s:
	Approval status of product in Reference Regulatory Authorities	Cannot be confirmed
	Me-too status	Velosef Injection Reg: No. 001866 Bristol Myer Squib Pakistan/GSK
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Previous Decision	• **Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were**

		declared/approved by the Registration Board (M-291)
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1054	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Volvocef 1g Injection
	Composition	Each vial contains: Cephradine with Sterile Arginine eq. to Cephradine.....1g
	Diary No. Date of R& I & fee	Dy. No. 8714 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	1's:
	Approval status of product in Reference Regulatory Authorities	Approved in National Agency for the Safety of Medicine and Health Products (ANSM), France
	Me-too status	Cannot be confirmed
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Previous remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Previous Decision	• **Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-291)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	
1055	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, Plot No.224/23, Korangi Industrial Area, Karachi (Dry powder injection vials Cephalosporin).
	Brand Name +Dosage Form + Strength	Cefrinex 1gm Dry powder for injection.
	Composition	Each vial contains: 1gm sterile cephradine with sterile arginine.
	Diary No. Date of R& I & fee	Dy. No 18914 dated 24-10-2017; Rs. 20,000/- dated 31-10-2016. Duplicate File Bearing Dy. No.151 dated 19-04-2021.
	Pharmacological Group	1st Gen Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP specifications.
	Pack size & Demanded Price	1's & As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Cefrinex vial 1000mg, Reg. No. 015129.
	GMP status	Same as above.

	Previous remarks of the Evaluator.	Firm has provided Velosef 1gm injection in HPRA (Ireland) which could not be verified. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Provided evidence is discontinued.
	Previous Decision	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. (M-316)**
	Evaluation by PEC	
	Decision: Approved with USP Specifications. **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.**	

Case No. 06 Cases in which firms have not yet submitted complete response.

1056	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Section approval letter dated 06-11-2019 specifying Dry Vial Injection section (Carbapenem).
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24364: 03-09-2021
	Details of fee submitted	PKR 50,000/-: 05-01-2021
	The proposed proprietary name / brand name	**NEXIDORE 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Doripenem Monohydrate Eq. to Doripenem…250mg
	Pharmaceutical form of applied drug	Glass vial filled with white to slightly yellowish, off white crystalline powder.

	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Finibax Intravenous Infusion 0.25g **(PMDA Japan** Approved)
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Firm has not submitted verification studies of analytical method for the testing of drug substance.**
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not performed by the firm
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	KOPRAN RESEARCH LABORATORIES LIMITED K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA		
API Lot No.	DIPV/B2002002, DPIV/P2001003, DPIV/P2001004		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DN-001	DN-002	DN-003
Batch Size	1200 vials	1200 vials	1200 vials
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	25-04-2020	25-04-2020	25-04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. KD/89275/2020/11/33788) issued by FDA Mahrashtra dated 20-10-2020. The certificate is valid till 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of Doripenem 3Kg from M/s Kopran Research Laboratories Limited K4/4, Additional MIDC, At & Post Birwadi, Taluka Mahad, District Raigad - 402 302 Maharashtra, INDIA issued by AD (I&E) DRAP field office. The license was issued on 08-04-2020. • Firm has submitted copy of commercial invoice cleared dated 08-04-2020 specifying import of 3Kg doripenem Batch No. DIPV/B2002002, DPIV/P2001003, DPIV/P2001004.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for two day 24-04-2020 and 25-04-2020.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP on 3rd September 2021.	
2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.
3.	Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised FPP specifications, method of analysis is submitted.
4.	Justify the use of drug substance having in house specifications while the drug substance specifications are present in JP monograph for "Doripenem hydrate"	Revised specification & method of analysis for Doripenem hydrate as per JP is submitted.
5.	Justify the limit of water from 4.0 – 5.5% in drug substance specifications, while JP monograph specifies the limit from 4.0 – 5.0%.	Drug substance was analyzed using a manufacturer specs and method of analysis at time of development. Moreover, in water contents of drug substance also qualifies the acceptance limit of JP.
6.	Justify why the test for residue on ignition is not performed for the drug substance since it is recommended in JP monograph.	Drug substance was analyzed using a manufacturer specs and method of analysis at time of development where residue on ignition wasn't part of specifications. Now revised specs is submitted.
7.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Specifications & method of analyses from Drug Substance & Drug Product manufacturers is submitted.
8.	Justify the use of a different analytical method for assay testing of drug substance from that specified in JP monograph. The method of drug substance manufacturer is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.	Drug substance was analyzed by using manufacturer's method of analysis at time of development that is why testing conditions differs from that of JP monograph. Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised drug substance specification & method of analysis as per JP is submitted.
9.	Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	At time to development we followed in-house method of analysis and submitted analytical method validation. We started following the JP at 12 months' study time-point. Now the Analytical Method Verification Protocol & Report is submitted.

10.	Justify how 260mg of Doripenem Monohydrate eq.to Doripenem is equivalent to 250mg of doripenem as per the label claim.	Molecular weight of Doripenem Monohydrate = 438.52 Molecular weight of Doripenem = 420.50 Factor = 438.52 / 420.50 = 1.04 Equivalent weight ofDoripenem monohydrate for 250mgDoripenem = 250 x 1.04 = 260mg
11.	Justify how the applied drug is to be supplied with 10ml of sodium chloride 0.9% solution, since the innovator product recommends different volume for reconstitution.	10ml of sodium chloride 0.9% solution is for primary reconstitution which will then be further diluted as per requirements.
12.	Justify why pharmaceutical equivalence studies are not performed.	As Nexidore 250mg injection is ready to fill product, and fill weight of 250mg injection is half of 500mg injection. There is no addition of any other contents in the formulation so pharmaceutical equivalence study has been done against dorinem 500mg injection by ICI Pakistan.
13.	The process validation protocols does not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.	Revised prospective process validation protocol is submitted.
14.	Justify the drug product specifications section (3.2.P.5.1) with water contents from 4.0% to 5.5% while the JP monograph for the drug product specifies water contents to be 4.0 to 5.0%.	Product specifications has been revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Moreover during stability study the water contents results also complies the JP limits(4-5%)
15.	Justify the limit of assay from 90 – 115% since the JP monograph specifies the assay limit from 95 – 105%.	Product specifications has been revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Moreover during stability study the Nexidore assay results also complies the JP limits(95-105%).
16.	Justify the use of a different analytical method for assay testing of drug product from that specified in JP monograph. The analytical method of drug product is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, total run time and retention time, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.	Drug substance was analyzed by using manufacturer's method of analysis at time of development that is why testing conditions differs from that of JP monograph. Product specifications are revised as per Japanese Pharmacopoeia referred to "supplement II to Japanese Pharmacopoeia seventeenth edition" notified on June 28th, 2019 and later on circulated. Revised specification & method of analysis for drug product as per JP is submitted.
17.	Justify the assay preparation step in the assay testing of drug product specifications in which the contents of only 1 vial is taken, justify how the contents taken from only 1 vial can be considered representative of the whole batch.	**No justification is provided by the firm.**
18.	Justify why the test of specificity is not performed during the validation studies of the analytical method of drug product.	Nexidore Injection is ready to fill product. It doesn't contain inactive ingredients, so there wouldn't need the test of specificity during validation studies.Now we are following JP method and analytical method verification study of product is attached with inclusion of specificity.
19.	Provide details of the concentration in mg/ml of different solutions i.e. 50% to 150% used in accuracy and precision testing during validation studies.	Concentration of 50% solution in mg/ml: 125/100 x 1/50 = 0.025mg/ml Concentration of 100% solution in mg/ml: 250/100 x 1/50 = 0.05mg/ml Concentration of 150% solution in mg/ml:

		375/100 x 1/50 = 0.075mg/ml **The concentration of standard solution recommended by JP is 0.125mg/ml which is different from the 100% concentration used by the firm.**
20.	Justify why the test of water contents and uniformity of dosage units is not performed in the batch analysis stage.	Both tests have now been performed on drug product
21.	Justify the release of drug product batches on 25-04-2020 after performing test of sterility, since the drug substance was released after testing on 24-04-2020. Justify how the three batches were manufactured and stability studies were being performed within 1 day only.	This is no GMP, non-commercial batch produced for R&D and stability purpose. In case of product development and stability batches the product does not have to go to market normally all test including sterility are started from zero point. Hence in case of product development in order to achieve stability time lines, all test can be started together. Since the product has to stay at stability for atleast three months so by the time sterility will come up and if any test fails the results will together come up.
22.	Justify the use of 25ml type-II glass vial for the applied drug product since as per your submission the drug product is to be reconstituted in 10ml normal saline.	It was typo error at time of submission. It is 15mL Type I glass vial.
23.	Justify how the results of initial time point is different at real time and accelerated stability data sheet for batch DN-001 and DN-002.	The product has been tested separately for real time and accelerated time stability that's why their results vary but it is in acceptable range.
24.	Justify how the results of pH and assay of batch DN-001 and DN-002 at initial time point in real time stability studies is exactly same.	It is typo error
25.	You have submitted that all stability batches were manufactured using the drug substance batch No. DPIV/P2001003. For manufacturing of 3 batches each having batch size 1200 vials, approximately 1.87Kg drug substance is required, while as per the clearance documents and commercial invoice 1Kg drug substance of batch number DPIV/P2001003 was imported. Justify how three batches were manufactured using the drug substance having batch number DPIV/P2001003.	Three stability batches were manufactured with 312gm of powder from each of 3 containers. Consumption detail of each API lots for manufacturing of three stability batches are: **Nexidore 250mg Injection (DN-001):** DPIV/B2002002 **Nexidore 250mg Injection (DN-002):** DPIV/P2001003 **Nexidore 250mg Injection (DN-003):** DPIV/P2001004 Firm has not submitted documents for import of these lots of API.
26.	Justify why stability testing was not performed for the drug product at the end of accelerated stability study.	We have already submitted complete accelerated stability study data (6 months). However, attaching again herewith for your review in Annexure 13.we are also providing 9th, 12th, 18th stability study data as per JP method.
27.	Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Submitted by the firm.

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

1057	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt) Ltd. E-127-129, North Western Industrial Zone Bin Qasim Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP inspection report dated 11-08-2020 concludes satisfactory compliance to GMP. Firm has submitted copy of GMP certificate of dated 16-09-2020 based on the inspection dated 28-08-2019. The GMP certificate specifies Tablet (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 24-09-2012 specifying Tablet section. Firm has submitted copy of GMP certificate of dated 16-09-2020 based on the inspection dated 28-08-2019. The GMP certificate specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29007: 25-10-2021
	Details of fee submitted	PKR 75,000/-: 02-07-2021
	The proposed proprietary name / brand name	**SAFIMIDE 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Safinamide as mesylate……100mg
	Pharmaceutical form of applied drug	Orange round biconvex film coated tablet
	Pharmacotherapeutic Group of (API)	Monoamine oxidase B inhibitors (N04BD03)
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xadago Tablets **(USFDA** Approved)
	For generic drugs (me-too status)	NA
	Clinical Indiciations and Use:	XADAGO is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.
	Name and address of API manufacturer.	Menovo Pharmaceutical Co. Ltd. 7 Wei 11 Road, Hangzhou Gulf Industrial Area, Shangyu Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

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

STABILITY STUDY DATA

Manufacturer of API	Menovo Pharmaceutical Co. Ltd. 7 Wei 11 Road, Hangzhou Gulf Industrial Area, Shangyu Zhejiang China.		
API Lot No.	PD/SAF/05/1511/02R		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TF#01	TF#02	TF#03
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	09-2019	09-2019	09-2019

Date of Initiation	21-10-2019	21-10-2019	21-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their last onsite inspection conducted for product Rofair (Roflumilast) 500mcg Tablets on 25th June, 2019. The said inspection report was discussed in 290th meeting of Registration Board held on 3rd–4th July, 2019 and the case was approved. The inspection report confirms following points: • The firm has Shimadzu 's LC 20A, with software ―Lab solution DB‖ which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate of M/s Zhejiang Menovo Pharmaceutical Co. Ltd. No. 8, Jing 13 Road, Hangzhou Gulf Shangyu Economic and Technological Development zone, Shangyu City Zhejiang Province China. Issued by Agency for medicinal products and medical devices of the republic of Slovenia on the basis of inspection dated 13-03-2017.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of proforma invoice number YP016 dated 26-03-2018 from Ningbo Menovo Pharmaceutical Co. Ltd. Specifying 750g safinamide mesylate. The Invoice is not cleared by AD (I&E). Firm has also submitted copy of DHL invoice with airway bill number 4495533405.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete stability data of 3 batches for 6 months.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance of HPLC system along with report of audit trail.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for accelerated and real time stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit complete label claim in section 1.5.2 stating complete description of product whther film coated tablet or otherwise along with exact salt form and quantity of drug substance contained, since you have only mentioned 100mg.	Each film coated tablet Contains: Safinamide as mesylate……100mg

2.	Submit data in section 3.2.S.3 regarding the characterization of drug substance and its IR spectra.	Firm has submitted characterization studies of the drug substance along with IR spectra.
3.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications and analytical method of drug substance from drug product manufacturer as well.
4.	Provide verification studies of drug substance from drug product manufacturer in section 3.2.S.4.3.	Firm has submitted analytical method verification studies of the drug substance.
5.	Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product in section 3.2.S.4.4, since COA of different batches is provided in this section.	Firm has submitted COA of relevant lot of API having batch number PD/SAF/05/1511/02R, from both API manufacturer as well as product manufacturer.
6.	Submit COA of reference standard used for analysis of drug substance in section 3.2.S.5.	Firm has submitted COA of reference standard.
7.	Submit Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component in section 3.2.S.6.	Firm has submitted complete details of section 3.2.S.6 with details of container closure system.
8.	Submit data in relevant section / sub-section of module 3.2.P instead of referring to annexures.	Firm has again submitted module 3.2.P as per CTD guidance document.
9.	Submit information and master formulation in section 3.2.P.1	Firm has submitted master formulation and description of drug product as per guidance document in section 3.2.P.1
10.	Submit complete details of all subsections related to pharmaceutical development in section 3.2.P.2 and its sub sections.	Firm has submitted section 3.2.P.2 as per CTD guidance document.
11.	Justify why the qualitative composition of product is different from that of innovator's product.	The composition of the product for core is same as innovator's product. The coating material used in innovator is hypromellose while we are using ready made coat Shef Coat in which polymer used is also hypromellose.
12.	Description of manufacturing process and process controls in section 3.2.P.3.3.	Firm has submitted description of manufacturing process and process controls for the applied formulation.
13.	Controls of critical steps and intermediates in section 3.2.P.3.4.	Firm has submitted controls of critical steps and intermediates for the applied formulation.
14.	You have mentioned product description as Orange round biconvex film coated tablet in section 3.2.P.1 and white round biconvex tablet in section 3.2.P.5.1. Justification is required in this regard.	It was a typo mistake in section 3.2.P.5.1.
15.	Justify the dissolution acceptance criteria NLT 75% in 30 minutes since the dissolution criteria of innovator's product is NLT(Q) in 20 minutes.	Complete dissolution profile (CDP) shows that our product attains 90% dissolution in 15 minutes. This is similar to the innovator's product more than 90% dissolution is achieved at 30 minutes. Dissolution is achieved at 30 minutes. In FDA dissolution guidelines the sampling time for safimide tablet are upto 45 minutes. That's why we have set dissolution criteria NLT 75% in 30 mins although our products meet this criteria in 15 minutes as that of innovator's product.
16.	Submit validation report of analytical method of drug product in section 3.2.P.5.3 instead of submitting raw data and chromatograms.	Firm has submitted validation report of analytical method of drug product.

17.	Submit batch analysis report of three batches in section 3.2.P.5.4.	Firm has submitted batch analysis report of three stability batches.
18.	Submit information in section 3.2.P.5.5 and 3.2.P.5.6.	Firm has submitted information of impurity characterization and justification of specifications in section 3.2.P.5.5. and 3.2.P.5.6.
19.	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.	Firm has submitted COA of reference standard.
20.	Submit complete details of container closure system of the drug product in section 3.2.P.7.	Firm has submitted details of container closure system.
21.	Submit details and information in section 3.2.P.8.1.	Firm has submitted summary and conclusion of stability studies batches in section 3.2.P.8.1
22.	Provide stability data submmary sheets of three batches of drug product as per the format provided in CTD guidance document in a proper sequence, since your submitted format does not contain information of API lot number and also not provided in any sequence.	Firm has submitted stability study data after proper arrangement in a sequence along with raw data sheets.
23.	The submitted chromatograms does not contain any details of the time of chromatogram acquisition and processing. Clarification is required in this regard.	There was a technical problem in software that's why time was not mentioned in chromatograms.
24.	• Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. o Record of Digital data logger for temperature and humidity monitoring of both stability chambers.	Firm has submitted data as per 6 points checklist.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Firm will revise the dissolution specifications to NLT(Q) in 20 minutes and perform dissolution test as per revised acceptance criteria for commercial batches.**

1058	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore.**

	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24214: 02-09-2021
	Details of fee submitted	PKR 75,000/-: 04-08-2021
	The proposed proprietary name / brand name	**PDFIM 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……100mg
	Pharmaceutical form of applied drug	White to light yellow powder filled in amber colored glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cebosh dry suspension of Bosch pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00243/342/2017		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180012	180013	180015
Batch Size	5,000 bottles	5,000 bottles	5,000 bottles
Manufacturing Date	02-2018	02-2018	04-2018
Date of Initiation	22-03-2018	19-03-2018	19-04-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous PSI has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 09-02-2018 specifying purchase of 25Kg Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, HPLC chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Registration Board in its 320th meeting considered the case of Cefixime 100mg/5ml dry suspension manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore wherein the Board decided to defer for following points for which the response is tabulated below:

Sr. No	Reasons for deferment	Response by the firm
1.	Scientific justification for having different specifications of the drug substance from that of API manufacturer as well as BP monograph	The firm has submitted revised specifications for drug substance as per B.P.
2.	Scientific justification how a revised method of February 2021 can represent the results of the stability studies which were initiated in March 2018.	The format of SOP For Cefixime was revised in February 2021. However, the testing method was same as that of stability studies initiated in 2018. We didn't change the testing method of API, only format was revised with new revision number and date.
3.	Scientific justification for performing verification studies of the analytical method of drug substance using a different analytical method from that specified in section 3.2.S.4.2.	The firm has stated that the verification studies were performed for analytical method as provided in the section 3.2.S.4.2. Furthermore, the calculation method is also as per B.P. The firm has submitted relevant chromatogram and raw data sheets.
4.	Submission of stability study data of three batches of cefixime trihydrate (micronized) from the API manufacturer as per zone IV-A conditions.	The firm has submitted stability study data of three batches (real time: 36 months : Accelerated : 06 months) according to the conditions of Zone IV-A. Batches: 00243/001/2018, 00243/100/2018, 00243/200/2018
5.	Submission of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product.	Pharmaceutical equivalence and CDP studies have been performed against Cefspan dry suspension mfg by M/s Barret Hodgson. The firm has submitted the relevant data including calculations of F2 values.
6.	Submission of preservative effectiveness studies.	The firm has performed preservative effectiveness studies and presented the data in relevant section (document no. SOP-MB/02-0238).
7.	Submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	The firm has submitted Rs. 7,500/- for revision of specifications vide challan number 947937869.
8.	Scientific justification how the results of at zero-month time point can be different for accelerated and real time conditions.	The results in raw data sheets are same for accelerated and real time stability at initial time point whereas in stability summary sheets the results are different, it was a typographical error. We are submitting revised stability summary sheets.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Registration Board noted the fact that since separate pharmacopoeial monograph is not available for different grades of Cefixime i.e., micronized and compacted, thereby the submitted stability studies of drug substance is acceptable hence Board approved the instant application. • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**		
1059	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24215: 02-09-2021
	Details of fee submitted	PKR 75,000/-: 04-08-2021
	The proposed proprietary name / brand name	**PDFIM 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	White to light yellow powder filled in amber colored glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cebosh dry suspension of Bosch pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00243/342/2017		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180011	180016	180048
Batch Size	5,000 bottles	5,000 bottles	5,000 bottles
Manufacturing Date	02-2018	04-2018	08-2018
Date of Initiation	19-03-2018	22-03-2018	22-03-2018

No. of Batches	03

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous PSI has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 09-02-2018 specifying purchase of 25Kg Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, HPLC chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Registration Board in its 320th meeting considered the case of Cefixime 200mg/5ml dry suspension manufactured by M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore wherein the Board decided to defer for following points for which the response is tabulated below:

Sr. No	Reasons for deferment	Response by the firm
1.	Scientific justification for having different specifications of the drug substance from that of API manufacturer as well as BP monograph	The firm has submitted revised specifications for drug substance as per B.P.
2.	Scientific justification how a revised method of February 2021 can represent the results of the stability studies which were initiated in March 2018.	The format of SOP For Cefixime was revised in February 2021. However, the testing method was same as that of stability studies initiated in 2018. We didn't change the testing method of API, only format was revised with new revision number and date.
3.	Scientific justification for performing verification studies of the analytical method of drug substance using a different analytical method from that specified in section 3.2.S.4.2.	The firm has stated that the verification studies were performed for analytical method as provided in the section 3.2.S.4.2. Furthermore, the calculation method is also as per B.P. The firm has submitted relevant chromatogram and raw data sheets.
4.	Submission of stability study data of three batches of cefixime trihydrate (micronized) from the API manufacturer as per zone IV-A conditions.	The firm has submitted stability study data of three batches (real time: 36 months : Accelerated : 06 months) according to the conditions of Zone IV-A. Batches: 00243/001/2018, 00243/100/2018, 00243/200/2018
5.	Submission of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product.	Pharmaceutical equivalence and CDP studies have been performed against Cefspan dry suspension mfg by M/s Barret Hodgson. The firm has submitted the relevant data including calculations of F2 values.
6.	Submission of preservative effectiveness studies.	The firm has performed preservative effectiveness studies and presented the data in relevant section (document no. SOP-MB/02-0238).
7.	Submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	The firm has not submitted any fee.
8.	Scientific justification how the results of at zero-month time point can be different for accelerated and real time conditions.	The results in raw data sheets are same for accelerated and real time stability at initial time point whereas in stability summary sheets the results are different, it was a typographical error. We are submitting revised stability summary sheets.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**

1060	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swat Pharmaceuticals, Saidu Sharif, Swat.**
	Name, address of Manufacturing site.	M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 24-02-2021.
	GMP status of the firm	Firm has submitted copy of inspection report of M/s EG Pharmaceuticals dated 13-02-2019 recommending the renewal of DML.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000752) dated 29-08-2012 specifying capsule (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12677: 29-04-2021
	Details of fee submitted	PKR 50,000/-: 15-03-2021
	The proposed proprietary name / brand name	**SOXIME 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton

	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has also submitted results of comparative dissolution profile of their product with Fixval Capsule of M/s GSK. Firm has performed CDP in 0.1 N HCl, buffer pH 4.5 and phosphate buffer pH 6.8. Firm also calculated factor f2 which was above 50. The firm has submitted results and comparison of Fixval Capsule, manufactured by M/s GSK and Ficx Capsule of M/s EG. Test results of this study found satisfactory, comparable and within specifications.
	Analytical method validation/verification of product	Firm has submitted analytical method validation data.

STABILITY STUDY DATA

Manufacturer of API	SAAKH PHARMA (Pvt)Ltd C-7/1,NWIZ,Port Qasim Karachi
API Lot No.	8CF10131,18CF10111,18CF10039
Description of Pack (Container closure system)	Alu-Alu blister in unit carton
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	961	990	933
Batch Size	3500 Packs	4370 Packs	4000 Packs
Manufacturing Date	03-2019	04-2019	02-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate 039/2019-DRAP (K) issued by the DRAP has been submitted. Which is valid up to 03-01-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A As API Purchased from Saakh Pharma (Pvt)Ltd C-7/1,NWIZ, Port Qasim Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

Evaluation by PEC:

Firm was issued letter of shortcomings with following points:

- The application for contract manufacturing from M/s EG Pharmaceuticals Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document.
- The drug product testing has been carried out using specifications which are not in line with the specifications of cefixime capsule approved by Registration Board, furthermore the firm has carried out dissolution testing using UV method and the assay test during stability studies are also carried out using a single chromatogram of standard and sample.
- Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board in which product development and stability studies has been conducted as per the monograph approved by Registration Board and notified vide No.F.14-1/2022-PEC dated 14-03-2022 along with submission of requisite fee so that further evaluation of your application could be carried out.

Response by the firm:

Firm has submitted that the same formulation of cefixime 400mg capsule manufactured by M/s EG Pharmaceuticals have been approved by Registration Board in its 296th meeting as a case of "*Request for Change in Registration Status of Product from M/s Swat Pharmaceuticals to M/s Wahabsons Pharma (Pvt) Ltd. Swat Through Contract Manufacturing at M/s EG Pharmaceuticals, Islamabad*".

Applicant firm	M/s Wahab sons pharma Pvt Ltd 4km Buner Road Barikot Swat
Manufacturer firm	EG Pharmaceuticals 13A Industrial Triangle, Kahuta road Islamabad
Brand Name	Soxime Capsules 400mg
Batch No. of drug product	961 (3500 Packs), 990 (4370 Packs), 933 (4000 Packs)

Case No.	1
Page number	2461-2463
Registration Board meeting	296th meeting of Registration Board.

Decision: Approved. Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

1061	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nortech Pharmaceuticals. Plot # 203, Sihala Industrial Triangle, Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 19-10-2020.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License of M/s Cure Laboratories (Pvt) Ltd dated 05-03-2019 specifying Capsule (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16050: 07-03-2019 (Form 5) Dy. No. 24216: 07-03-2019 (Form 5-F)
	Details of fee submitted	PKR 50,000/-: 23-11-2020
	The proposed proprietary name / brand name	**NORXIME 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T022	T023	T024
Batch Size	500 ampoules	500 ampoules	500 ampoules
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

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

Evaluation by PEC:

Firm has initially applied for contract manufacturing with Mediate Pharmaceuticals on Form 5 on 07-03-2019. Later the firm on 02-09-2021 submitted Form 5F along with change of contract manufacturer to M/s Cure Laboratories Islamabad without submission of fee.

- Submission of fee PKR 75,000/- for change of contract manufacturer from Mediate Pharmaceuticals to Cure Laboratories.
- The application for contract manufacturing from M/s Cure Laboratories Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document.
- The drug product testing has been carried out using specifications which are not in line with the specifications of cefixime capsule approved by Registration Board, furthermore the firm has carried out assay and dissolution testing using UV method while their own specifications specify HPLC method for assay.
- Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board in which product development and stability studies has been conducted as per the monograph approved by Registration Board and notified vide No.F.14-1/2022-PEC dated 14-03-2022 along with submission of requisite fee so that further evaluation of your application could be carried out.

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

1062	**Name, address of Applicant / Marketing Authorization Holder**	**M/s TN Pharmaceuticals (Pvt) Ltd. Plot No. 264-C, Sunder Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s TN Pharmaceuticals (Pvt) Ltd. Plot No. 264-C, Sunder Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 22-03-2019 issued on the basis of inspection dated 01-03-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manuacturing License (DML) dated 21-07-2017 specifying Tablet (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 21248: 28-07-2022
	Details of fee submitted	PKR 30,000/-: 18-07-2022
	The proposed proprietary name / brand name	**PARATIN 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol ……500mg
	Pharmaceutical form of applied drug	white color round uncoated tablet
	Pharmacotherapeutic Group of (API)	Analgesic / antipyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol IPCA 500mg Tablet by IPCA Laboratories (**MHRA** Approved)
	For generic drugs (me-too status)	Panadol Tablet of M/s GSK Pakistan (Reg # 000817)
	Name and address of API manufacturer.	Citi Pharma (Pvt) Ltd., 3-Km Head Balloki Road, Phool Nagar Kasur.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests defined in BP for their product against the reference product i.e. Panadol tablet of GSK. Firm has submitted results of CDP in three dissolution medium for their product against the reference product i.e. Panadol tablet of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Citi Pharma (Pvt) Ltd., 3-Km Head Balloki Road, Phool Nagar Kasur.		
API Lot No.	Not submitted		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRL-28	TRL-29	TRL-30
Batch Size	500 Tablet	500 Tablet	500 Tablet
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	14-06-2021	14-06-2021	14-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine

testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."

- Provide verification studies of drug substance from drug product manufacturer.
- Provide COA of relevant batch of drug substance which is used in the manufacturing of batches of drug product.
- Justify why qualitative composition is different from the reference product, or else submit drug-excipient compatibility studies.
- Justify why the analytical procedures of the drug product are different from that specified in latest edition of USP monograph. Furthermore, submit detailed analytical procedure instead of attaching monograph of USP 29.
- Provide detailed analytical procedures and exact concentrations of sample solutions used to perform verification studies.
- Provide batch analysis report in section 3.2.P.5.4 instead of attaching BMR.
- Provide COA of reference standard actually used in the analysis of drug substance and drug product.
- Justify significant change in assay from 106.31% to 99.89% in accelerated stability of Batch TRL-28.
- Justify significant change in assay from 106.23% to 99.58% in accelerated stability of Batch TRL-29.
- Justify why you have performed stability studies using HPLC analysis performed at different column length, diameter and column temperature from that specified in USP monograph.
- Provide evidence of gradient HPLC system which is required as per USP monograph.
- Provide reference of previous approval of applications with stability study data of the firm (if any)
- Provide evidence of approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Provide copy of commercial invoice for evidence of purchase of the drug substance.
- Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

1063	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25, Sector 20, K.I.A., Karachi**
	Name, address of Manufacturing site.	M/s Liven Pharmaceuticals (Pvt) Ltd, 49-Km, Lahore Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted contract manufacturing agreement dated 29-04-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 31-07-2019 based on the inspection dated 03-07-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000881) dated 11-04-2018 specifying Liquid Injection Ampoule (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25802: 16-09-2021
	Details of fee submitted	PKR 50,000/-: 08-05-2021 + PKR 25,000/-: 07-06-2021
	The proposed proprietary name / brand name	**ONDASET 4mg/2ml Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ondansetron (as HCl)……4mg
	Pharmaceutical form of applied drug	Clear colorless liquid filled in clear glass ampoule
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**MHRA** Approved)
	For generic drugs (me-too status)	Onseron Injection by Indus Pharma
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.

API Lot No.	180S002		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ON1	ON2	ON3
Batch Size	25000 Ampoules	25000 Ampoules	25000 Ampoules
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	08-06-2019	10-06-2019	13-06-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 18101065) issued by Food and Drugs Control Administration Gujrat Estate India. The certificate is valid till 18-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 3Kg Ondansetron hydrochloride cleared dated 16-04-2019. The invoice is cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed stability studies using UV method.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.
- Provide stability studies of three batches of drug substance as per zone IV-A conditions.
- Your qualitative composition is different from that of the innovator product. Justification is required in this regard.
- Innovator product has used ondansetron hydrochloride dehydrate while you are using ondansetron hydrochloride. Justification is required in this regard.
- Provide details incuding batch number, exppiry date and manufacturer of the product against which pharmaceutical equivalence studies are conducted, since Zofran 4mg/2ml injection is not registered in Pakistan.
- Justify the UV method as alternate method in the analytical procedure for assay test of your product, since no such test is specified in USP monograph.

• Justify the analytical method validation studies performed on UV method while USP as well as your analytical procedure specifies HPLC test. • Justify the performance of assay method using UV method which is contrary to the USP method for your commercial batches. • Provide reference of previous approval of applications with stability study data of the firm (if any) / previous product specific inspection. • Submit Batch Manufacturing Record of three stability batches.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1064	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma (Pvt) Ltd. Plot No. 10 & 25, Sector 20, K.I.A., Karachi**
	Name, address of Manufacturing site.	M/s Liven Pharmaceuticals (Pvt) Ltd, 49-Km, Lahore Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted contract manufacturing agreement dated 29-04-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 31-07-2019 based on the inspection dated 03-07-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000881) dated 11-04-2018 specifying Liquid Injection Ampoule (General) Section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25803: 16-09-2021
	Details of fee submitted	PKR 50,000/-: 08-05-2021 + PKR 25,000/-: 07-06-2021
	The proposed proprietary name / brand name	**ONDASET 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains: Ondansetron (as HCl)……8mg
	Pharmaceutical form of applied drug	Clear colorless liquid filled in clear glass ampoule
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	(**MHRA** Approved)
	For generic drugs (me-too status)	Onseron Injection by Indus Pharma
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

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

STABILITY STUDY DATA

Manufacturer of API	M/s Cadila Pharmaceuticals Ltd. 294, G.I.D.C, Estate, Ankleshwar District Bharuch Gujrat Estate, India.		
API Lot No.	180S002		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OT1	OT2	OT3
Batch Size	25000 Ampoules	25000 Ampoules	25000 Ampoules
Manufacturing Date	04-2019	05-2019	06-2019
Date of Initiation	31-05-2019	15-06-2019	27-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 18101065) issued by Food and Drugs Control Administration Gujrat Estate India. The certificate is valid till 18-10-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 3Kg Ondansetron hydrochloride cleared dated 16-04-2019. The invoice is cleared by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has performed stability studies using UV method.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.
- Provide stability studies of three batches of drug substance as per zone IV-A conditions.
- Your qualitative composition is different from that of the innovator product. Justification is required in this regard.
- Innovator product has used ondansetron hydrochloride dehydrate while you are using ondansetron hydrochloride. Justification is required in this regard.
- Provide details incuding batch number, exppiry date and manufacturer of the product against which pharmaceutical equivalence studies are conducted, since Zofran 4mg/2ml injection is not registered in Pakistan.
- Justify the UV method as alternate method in the analytical procedure for assay test of your product, since no such test is specified in USP monograph.
- Justify the analytical method validation studies performed on UV method while USP as well as your analytical procedure specifies HPLC test.
- Justify the performance of assay method using UV method which is contrary to the USP method for your commercial batches.
- Provide reference of previous approval of applications with stability study data of the firm (if any) / previous product specific inspection.
- Submit Batch Manufacturing Record of three stability batches.
- Batch OT3 is manufactured on 06-2019 and placed on stability studies on 27-08-2019. Justification is required in this regard.

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

1065	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Farm Aid Group Pharmaceuticals, 3/2 Phase-I & II Hattar Industrial Estate Hattar, Haripur.**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 19-10-2020.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License of M/s Cure Laboratories (Pvt) Ltd dated 05-03-2019 specifying Capsule (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22587: 17-08-2021
	Details of fee submitted	PKR 50,000/-: 23-11-2020
	The proposed proprietary name / brand name	**FOFAM 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	

	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	

STABILITY STUDY DATA

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

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

- The application for contract manufacturing from M/s Cure Laboratories Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document.
- The drug product testing has been carried out using specifications which are not in line with the specifications of cefixime capsule approved by Registration Board, furthermore the firm has carried out assay and dissolution testing using UV method while their own specifications specify HPLC method for assay.

• Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board in which product development and stability studies has been conducted as per the monograph approved by Registration Board and notified vide No.F.14-1/2022-PEC dated 14-03-2022 along with submission of requisite fee so that further evaluation of your application could be carried out.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1066.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 24-02-2021.
	GMP status of the firm	Firm has submitted copy of inspection report of M/s EG Pharmaceuticals dated 13-02-2019 recommending the renewal of DML.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000752) dated 29-08-2012 specifying capsule (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23181: 25-08-2021
	Details of fee submitted	PKR 75,000/-: 21-06-2021
	The proposed proprietary name / brand name	**CEFINAG 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

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

Evaluation by PEC:

- The application for contract manufacturing from M/s EG Pharmaceuticals Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document.
- The drug product testing has been carried out using specifications which are not in line with the specifications of cefixime capsule approved by Registration Board, furthermore the firm has carried out dissolution testing using UV method and the assay test during stability studies are also carried out using a single chromatogram of standard and sample.
- Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board in which product development and stability studies has been conducted as per the monograph approved by Registration Board and notified vide No.F.14-1/2022-PEC dated 14-03-2022 along with submission of requisite fee so that further evaluation of your application could be carried out.

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

1067.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cherwel Pharmaceuticals (Pvt) Ltd. Plot No. 20, Phase 4, Hattar-Industrial Estate, KPK.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted notarized copy of contract manufacturing agreement with applicant firm dated 21-04-2017.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21171: 03-08-2021
	Details of fee submitted	PKR 50,000/-: 24-02-2021

	The proposed proprietary name / brand name	**Sunray Injection 5mg/mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Cholecalciferol……5mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cholecalciferol Injection **(ANSM** France Approved)
	For generic drugs (me-too status)	Novel-D Injection by Danas Pharma (Reg #073183)
	Name and address of API manufacturer.	Fermenta Biotech Limited. Village Takoli P.O. Nagwain, Dist Mandi Himachal Pradesh India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Novel-D Injection 5mg/ml.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA			
Manufacturer of API	Sichuan Yuxin Pharmaceutical Co., Ltd. No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (South District) Shifang city, Sichuan Province China.		
API Lot No.	B-1-51-M191210		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T022	T023	T024
Batch Size	500 ampoules	500 ampoules	500 ampoules
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

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

Evaluation by PEC:

- *The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document. Furthermore, it is also pertinent to mention that the drug product testing has been carried out using specifications which are not in line with the recommendations of the general monographs of the official pharmacopoeia and the analytical method of the assay test is based on UV method contrary to the method of analysis of the drug substance manufacturer and the method of analysis specified in section 3.2.P.5.2.*
- *Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board and also justifying the specifications of the drug product so that further evaluation of your application could be carried out.*

In response, the firm has submitted stability study data of new batches manufactured using a different lot of API. The evaluation of newly submitted data is as under:

STABILITY STUDY DATA

Manufacturer of API	Sichuan Yuxin Pharmaceutical Co., Ltd. No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (South District) Shifang city, Sichuan Province China.		
API Lot No.	B-1-51-M180903		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-644	A-645	A-646
Batch Size	30,000 packs	30,000 packs	30,000 packs
Manufacturing Date	05-2019	05-2019	05-2019
Date of Initiation	27-05-2019	27-05-2019	27-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SC20160032) issued by CFDA China. The certificate **was valid till 17-11-2021**.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice for import of Vitamin D3 API having lot number B-1-51-M180903. The invoice is cleared by AD (I&E) dated 29-10-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted copy of clearance certificate specifying import of 2.5Kg API dated 29-10-2018.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 75,000/- fee for revision in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1068.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Albert Pharmaceuticals (Pvt) Ltd. Plot No. 127, Sundar Industrial Estate, Raiwind Road, Lahore.**

	Name, address of Manufacturing site.	M/s Himedic Pharmaceuticals (Pvt) Ltd. 19 Km Link Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted notarized copy of contract manufacturing agreement with applicant firm dated 04-05-2021.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Himedic Pharmaceuticals dated 05-08-2015. The letter specifies dry powder for injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23879: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 30-06-2021
	The proposed proprietary name / brand name	**ALZON Powder for Injection 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 250mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.		
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

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

Evaluation by PEC:

- Specify whther the application is for Intravenous or intra muscular use.
- Provide valid GMP certificate / inspection report of the contract manufacturer as well as applicant firm.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Provide COA of relevant batch of drug substace in section 3.2.S.4.4 used in the manufacturing of three batches of drug product for which stability data is submitted.
- Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
- Submit stability study data of drug substance conducted as per zone IV-A conditions or else submit the following as per the decision of 290th meeting of Registration Board:
    - Record of data logger for the storage conditions throughout the transportation of drug substance.
    - Real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.
- Justify your composition of drug product which specifies that the product contains ceftriaxone sodium 250mg while as per your label claim and innovator's product, the product shall contain 250mg of ceftriaxone as ceftriaxone sodium salt.
- The innovator product Rocephin Injection 250mg have specified that 2.4ml WFI is required to reconstitute the injection for intravenous injection, while you are using 5ml WFI. Justify why you are not using the same volume of diluent as specified by the innovator product.
- Justify the use of 5% overage in your commercially manufactured batches as well as during product development studies.
- Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. as per the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed."
- You have specified sample solution 1 method in your assay test while is acceptance criteria is for sample solution 2 method. Jutify this practice along with revision of specifications as per monograph and submission of fee.
- USP monograph specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria for assay test, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.
- Justify why the analytical procedure used in validation studies is different from that specified in your section 3.2.S.4.2.
- Validation studies are performed in 2021 while the stability study data is provided for batches of drug product which were manufactured before 2021.
- Justify how a single validation studies are used for all strengths of ceftriaxone injection since USP monograph specifies different analytical method for each strength.

- Provide batch release certificate of 3 batches of drug product in section 3.2.P.5.4 for which complete stability study data is provided in section 3.2.P.8.3. Since you have submitted batch release of different batches.
- Justify how you are using working standard from pharmagen while your drug substance source is Zhuhai United Laboratories.
- Provide details in section 3.2.P.8.1 as per CTD guidance document since this section is not submitted.
- Provide details in section 3.2.P.8.2 as per CTD guidance document since this section is not submitted.
- Provide summary sheets for stability studies data of 3 batches of drug product in section 3.2.P.8.3 as per the format approved by the Board and presented in CTD guidance document since your reports are hand written and not clearly visible and also does not provide information regarding particular lot number of the drug substance used to manufacture this particular batch of drug product.
- Provide documents for the procurement of relevant lot(s) of API used in the manufacturing of 3 batches of drug product for which stability studies data is submitted in section 3.2.P.8.3
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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

1069.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Albert Pharmaceuticals (Pvt) Ltd. Plot No. 127, Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Himedic Pharmaceuticals (Pvt) Ltd. 19 Km Link Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted notarized copy of contract manufacturing agreement with applicant firm dated 04-05-2021.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Himedic Pharmaceuticals dated 05-08-2015. The letter specifies dry powder for injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23880: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 30-06-2021
	The proposed proprietary name / brand name	**ALZON Powder for Injection 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……500mg

	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 250mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.

API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

- Specify whther the application is for Intravenous or intra muscular use.
- Provide valid GMP certificate / inspection report of the contract manufacturer as well as applicant firm.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Provide COA of relevant batch of drug substace in section 3.2.S.4.4 used in the manufacturing of three batches of drug product for which stability data is submitted.
- Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
- Submit stability study data of drug substance conducted as per zone IV-A conditions or else submit the following as per the decision of 290th meeting of Registration Board:
    - Record of data logger for the storage conditions throughout the transportation of drug substance.

- Real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.

- Justify your composition of drug product which specifies that the product contains ceftriaxone sodium 500mg while as per your label claim and innovator's product, the product shall contain 500mg of ceftriaxone as ceftriaxone sodium salt.
- Jutify the use of 5ml water for injection as a diluent for applied prouct in the line of innovator's drug product.
- Justify the use of 5% overage in your commercially manufactured batches as well as during product development studies.
- Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. as per the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed."
- You have specified sample solution 1 method in your assay test while is acceptance criteria is for sample solution 2 method. Jutify this practice along with revision of specifications as per monograph and submission of fee.
- USP monograph specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria for assay test, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.
- Justify why the analytical procedure used in validation studies is different from that specified in your section 3.2.S.4.2.
- Validation studies are performed in 2021 while the stability study data is provided for batches of drug product which were manufactured before 2021.
- Justify how a single validation studies are used for all strengths of ceftriaxone injection since USP monograph specifies different analytical method for each strength.
- Provide batch release certificate of 3 batches of drug product in section 3.2.P.5.4 for which complete stability study data is provided in section 3.2.P.8.3. Since you have submitted batch release of different batches.
- Justify how you are using working standard from pharmagen while your drug substance source is Zhuhai United Laboratories.
- Provide details in section 3.2.P.8.1 as per CTD guidance document since this section is not submitted.
- Provide details in section 3.2.P.8.2 as per CTD guidance document since this section is not submitted.
- Provide summary sheets for stability studies data of 3 batches of drug product in section 3.2.P.8.3 as per the format approved by the Board and presented in CTD guidance document since your reports are hand written and not clearly visible and also does not provide information regarding particular lot number of the drug substance used to manufacture this particular batch of drug product.
- Provide documents for the procurement of relevant lot(s) of API used in the manufacturing of 3 batches of drug product for which stability studies data is submitted in section 3.2.P.8.3
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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

1070.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Albert Pharmaceuticals (Pvt) Ltd. Plot No. 127, Sundar Industrial Estate, Raiwind Road, Lahore.**

	Name, address of Manufacturing site.	M/s Himedic Pharmaceuticals (Pvt) Ltd. 19 Km Link Multan Road, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted notarized copy of contract manufacturing agreement with applicant firm dated 04-05-2021.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Himedic Pharmaceuticals dated 05-08-2015. The letter specifies dry powder for injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23881: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 30-06-2021
	The proposed proprietary name / brand name	**ALZON Powder for Injection 1g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……1g
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 250mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.		
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

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

Evaluation by PEC:

- Specify whther the application is for Intravenous or intra muscular use.
- Provide valid GMP certificate / inspection report of the contract manufacturer as well as applicant firm.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Provide COA of relevant batch of drug substace in section 3.2.S.4.4 used in the manufacturing of three batches of drug product for which stability data is submitted.
- Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
- Submit stability study data of drug substance conducted as per zone IV-A conditions or else submit the following as per the decision of 290th meeting of Registration Board:
    - Record of data logger for the storage conditions throughout the transportation of drug substance.
    - Real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.
- Justify your composition of drug product which specifies that the product contains ceftriaxone sodium 1000mg while as per your label claim and innovator's product, the product shall contain 1000mg of ceftriaxone as ceftriaxone sodium salt.
- Jutify the use of 10ml water for injection as a diluent for applied prouct in the line of innovator's drug product.
- Justify the use of 5% overage in your commercially manufactured batches as well as during product development studies.
- Submit data of pharmaceutical equivalence in section 3.2.P.2.2.1. as per the decision of 293rd meeting of Registration Board, which states that "Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product should be submitted and discussed."
- You have specified sample solution 1 method in your assay test while is acceptance criteria is for sample solution 2 method. Jutify this practice along with revision of specifications as per monograph and submission of fee.
- USP monograph specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria for assay test, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.
- Justify why the analytical procedure used in validation studies is different from that specified in your section 3.2.S.4.2.
- Validation studies are performed in 2021 while the stability study data is provided for batches of drug product which were manufactured before 2021.
- Justify how a single validation studies are used for all strengths of ceftriaxone injection since USP monograph specifies different analytical method for each strength.

- Provide batch release certificate of 3 batches of drug product in section 3.2.P.5.4 for which complete stability study data is provided in section 3.2.P.8.3. Since you have submitted batch release of different batches.
- Justify how you are using working standard from pharmagen while your drug substance source is Zhuhai United Laboratories.
- Provide details in section 3.2.P.8.1 as per CTD guidance document since this section is not submitted.
- Provide details in section 3.2.P.8.2 as per CTD guidance document since this section is not submitted.
- Provide summary sheets for stability studies data of 3 batches of drug product in section 3.2.P.8.3 as per the format approved by the Board and presented in CTD guidance document since your reports are hand written and not clearly visible and also does not provide information regarding particular lot number of the drug substance used to manufacture this particular batch of drug product.
- Provide documents for the procurement of relevant lot(s) of API used in the manufacturing of 3 batches of drug product for which stability studies data is submitted in section 3.2.P.8.3
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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

1071.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23854: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 08-06-2021

	The proposed proprietary name / brand name	**GENXONE Dry Powder Injection 250mg (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 250mg Injection.

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

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.		
API Lot No.	3051805046		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180054	180075	180087
Batch Size	16666 vials	16666 vials	16666 vials
Manufacturing Date	09-2018	11-2018	12-2018
Date of Initiation	09-2018	11-2018	12-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20180909) issued by CFDA China. The certificate is valid till 05-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 03-07-2018 specifying import of 80Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide valid GMP certificate / inspection report of the contract manufacturer since the submitted GMP certificate has been expired.	The firm has submitted last inspection report dated 01/04/2019. The firm has maintained conformance to GMP compliance in manufacturing and QC operations.
2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.

3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Copies of the drug substance specifications and analytical procedures used for routine testing of drug substance by both drug product and drug substance manufacturer in the relevant sections as per guidance document for Form 5F.
4.	Provide details of the analytical method and concentrations in terms of mg/ml used to test the parameters in verification / validation studies of the drug substance. Further justify significant difference in peak areas value at same concentration during different tests like precision and accuracy/linearity.	The firm has submitted analytical method verification studies (including specificity, precision and accuracy etc) with the detail of concentrations of different dilutions used to test the parameters of required studies. Furthermore, different analyst were involve in the said testing therefore the results are not exactly the same.
5.	Justify why the test of specificity is not performed during the verification / validation studies of the drug substance.	The firm has submitted analytical method verification report mentioning the results of the test for specificity parameter for analytical method verification studies for dug substance performed by drug product manufacturer.
6.	The commercial invoice specifying ceftriaxone sodium sterile (USP) having batch number 3051805046 was cleared by AD (I&E) DRAP Lahore on 03-07-2018, while as per the certificate of analysis of raw material from Cunningham Pharmaceuticals, the material of same batch number was received on 05-01-2018 and was tested on 13-01-2018. Justification is required in this regard.	*It was a typographical error, the drug substance was received on 05/07/2018 and tested on 13/07/2018.*
7.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Certificate of analysis of reference standard actually used in the development of the applied product is provided.
8.	Justify how 300mg ceftriaxone sodium sterile powder is equivalent to 250mg of ceftriaxone base.	The firm has submitted revised calculation for potency adjustment considering the assay value of drug substance and stated that the calculations for potency adjustment will be made in future according to the assay value of the drug substance for commercial batches.
9.	The innovator product Rocephin Injection 250mg have specified that 2.4ml WFI is required to reconstitute the injection for intravenous injection, while you are using 5ml WFI. Justify why you are not using the same volume of diluent as specified by the innovator product.	The firm has stated that the volume of diluent used was exactly 2.4mL as recommended by the innovator's product. In the submitted data the volume used is 5mL which is a typographical error.
10.	You have specified that pharmaceutical equivalence studies was performed against Rocephin 250mg injection of Martin Dow Limited, while Rocephin 250mg Injection is not registered in Pakistan. Justification is required in this regard.	The firm has submitted pharmaceutical equivalence data agaisnt Oxidil 250mh injection mfg by Sami Pharmaceuticals by performing all the quality tests. Pharamcetuical equivalence against the other strengths of Ceftriaxone was performed against Rocephin and the data of ther strength was placed mistakenly in the dossier.
11.	Provide details of sample solution 2 preparation i.e. exact volume of water required for initial constitution of the ceftriaxone for injection.	Detail of preparation of sample solution II is provided in the relevant section which is in-lined with USP for the applied product.
12.	Your analytical method for drug product specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria as per USP monograph, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.	Specifications of finished product has been revised with addition of acceptance criteria for assay as per USP monograph. Revised specifications are submitted which are in-lined with USP. The firm has stated that they have performed one test at the stage of drug substance analysis and the other test is performed at the drug product stage. "*as we are dealing with the toll manufacturing in order for better understanding on COA we opted the 90-115% assay specifications. However, we have revised the SOP along with the specifications and would update and align all the practices and documents".*
13.	Certificate of analysis of finished product for batch number 180054 and batch number 180075 have same results for all the tests. Justification is required in this regard.	*It was a typographical error. We are submitted the COA for 180054 and 180075 having actual values for all the tests.*

14.	Batch number 180075 was manufactured in 11-2018 and its analysis was performed on 31-11-2018 while the batch was released on 19-09-2018. Justification is required in this regard.	*Due to typographical error, the date of release was mentioned as 19/09/2018. However, we are submitted the complete data for your convenience related to testing and release of the batch.*
15.	Provide date of initiation and date of testing at each time point for every batch during stability studies.	Submitted.
16.	Justify why the test for water contents, constituted solution etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life.	*We were not performing these tests in our stability testing. Whereas these tests were part of our routine testing.* The firm has performed water content determination test and submitted that relevant data.
17.	Justify how the results of assay and pH of each batch is different at initial time point for accelerated and real time stability study. The results of assay test at initial time point for each batch is different in stability summary sheet and raw data sheets. Justification is required in this regard.	*Results of assay and pH at initial time point are not different. This was a typographical error. We are submitting revised summary sheets with correct value of assay and pH.*
18.	Provide 6 months stability study data of three batches along with HPLC chromatograms and raw data sheets in a proper sequence and with separators as per the guidelines of registration Board for further evaluation.	The firm has submitted the stability study data as per the guidance document available on the official website of DRAP.
19.	Stability study data of initial time point is not submitted for any batch along with stability studies.	The firm has submitted the required data alongwith raw data sheets and chromatograms.
20.	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. o Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board. • Lenzeu 30mg and 60mg Capsule (Dexlansoprazol) approved in 297th meeting. & Tazipera 45g injection approved in 316th meeting. • Copy of GMP certificate No. GD20180909 valid till 05/12/2023, M/s Zhuhai United Laboratories Co., Ltd., issued by CFDA. • Firm has submitted copy of commercial invoice cleared dated 28-05-2020 specifying import of 100Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP. • Raw data sheet sand chromatograms have been submitted by the firm. • The firm has submitted record of digital data logger for accelerated and real time stability studies in the relevant section. • Compliance record of HPLC & audit trails are submitted.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**

1072.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.**

	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23853: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 08-06-2021
	The proposed proprietary name / brand name	**GENXONE Dry Powder Injection 250mg (IM)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 250mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.		
API Lot No.	3051805046		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180054	180075	180087
Batch Size	16666 vials	16666 vials	16666 vials
Manufacturing Date	09-2018	11-2018	12-2018
Date of Initiation	09-2018	11-2018	12-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20180909) issued by CFDA China. The certificate is valid till 05-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 03-07-2018 specifying import of 80Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide valid GMP certificate / inspection report of the contract manufacturer since the submitted GMP certificate has been expired.	The firm has submitted last inspection report dated 01/04/2019. The firm has maintained conformance to GMP compliance in manufacturing and QC operations.
2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Copies of the drug substance specifications and analytical procedures used for routine testing of drug substance by both drug product and drug substance manufacturer in the relevant sections as per guidance document for Form 5F.
4.	Provide details of the analytical method and concentrations in terms of mg/ml used to test the parameters in verification / validation studies of the drug substance. Further justify significant difference in peak areas value at same concentration during different tests like precision and accuracy/linearity.	The firm has submitted analytical method verification studies (including specificity, precision and accuracy etc) with the detail of concentrations of different dilutions used to test the parameters of required studies.
5.	Justify why the test of specificity is not performed during the verification / validation studies of the drug substance.	The firm has submitted analytical method verification report mentioning the results of the test for specificity parameter for analytical method verification studies for dug substance performed by drug product manufacturer.
6.	The commercial invoice specifying ceftriaxone sodium sterile (USP) having batch number 3051805046 was cleared by AD (I&E) DRAP Lahore on 03-07-2018, while as per the certificate of analysis of raw material from Cunningham Pharmaceuticals, the material of same batch number was received on 05-01-2018 and was tested on 13-01-2018. Justification is required in this regard.	The firm has stated that separate batches of drug substance were used or manufacturing of different strengths. Firm has submitted copy of commercial invoice cleared dated 19/11/2021 vide dy.no. 17452/2021-DRAP. The invoice is cleared by AD (I&E) DRAP.
7.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Certificate of analysis of reference standard actually used in the development of the applied product is provided.

8.	Justify how same results of pharmaceutical equivalence are produced for ceftriaxone 250mg IM and IV injection.	The firm has submitted pharmaceutical equivalence against Oxidil 250mg injection mfg by M/s Sami Pharmaceuticals by performing all the quality tests.
9.	Justify how 300mg ceftriaxone sodium sterile powder is equivalent to 250mg of ceftriaxone base.	
10.	Justify how you have manufactured batch number 200076 for axitrim 250mg IM as well as IV while both products have seprate registration numbers and have different analytical method for analysis.	The firm has submitted complete batch manufacturing record for 250mg IM injection for 3 batches along with the complete stability studies with the detail analytical method and other relevant documents.
11.	You have specified that pharmaceutical equivalence studies was performed against Rocephin 250mg injection of Martin Dow Limited, while Rocephin 250mg Injection is not registered in Pakistan. Justification is required in this regard.	The firm has submitted Pharmaceutical equivalence data against Oxidil 250mg Injecciton (Batch number : 014H mfg by M/s Sami Pharma) by performing quality tests.
12.	Justify how compatibility studies of IV injection can be used for ceftriaxone IM injection as well	The firm has submitted compatibility studies for 250mg IM injection with the recommended diluent. The data is presented in the relevant section (0H, 4H, 8H & 16H).
13.	Provide details of sample solution 2 preparation i.e. exact volume of water required for initial constitution of the ceftriaxone for injection.	Detail of preparation of sample solution II is provided in the relevant section which is in-lined with USP for 250mg IM injection.
14.	Your analytical method for drug product specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria as per USP monograph, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.	Specifications of finished product has been revised with addition of acceptance criteria for assay as per USP monograph. Revised specifications are submitted which are in-lined with USP. The firm has stated that they have performed one test at the stage of drug substance analysis and the other test is performed at the drug product stage. "*as we are dealing with the toll manufacturing in order for better understanding on COA we opted the 90-115% assay specifications. However, we have revised the SOP along with the specifications and would update and align all the practices and documents".*
15.	Justify how you are releasing commercial batches of ceftriaxone 250mg IM and IV as a single batch by producing two COA having exactly same results for each test.	Data of 250mg IM injection has been submitted with separate COAs. Certificate of Analysis of finished products are attached in executed BMRS of three batches enclosed in module 3 section 3.2.R.
16.	Justify how Batch number 180054, 180075 and 180087 submitted for IV injection are also used for IM injection.	The firm has submitted stability summary sheets for 250mg IM injection along with the relevant chromatograms and raw data sheets. The firm has stated that the data of 250mg IV injection was placed in 250mgIV dossier mistakenly.
17.	Justify how single BMR can be used for a single batch of two separately registered products like ceftriaxone 250mg IM and 250mg IV Injection.	Separate BMRs for 250mg ceftriaxone IM injection is submitted in section 3.2.R.1.2 along with the blank template of BM. The firm has submitted that the BMR were placed in 250mg IM injection mistakenly in the dossier on 250mg IV injection.
18.	Submit product development and stability study data of 3 batches of ceftriaxone 250mg IM injection for further evaluation.	The firm has submitted product development and stability study data of 3 batches of Ceftriaxone 250mg IM Injection along with the raw data sheets chromatograms, COAs etc.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved.

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

• **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**		
1073	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23857: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 08-06-2021
	The proposed proprietary name / brand name	**GENXONE Dry Powder Injection 500mg (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 500mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.		
API Lot No.	3051805046 3051805005		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180004	180019	180040
Batch Size	16666 vials	16666 vials	16666 vials

Manufacturing Date	01-2018	05-2018	07-2018
Date of Initiation	01-2018	05-2018	07-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20180909) issued by CFDA China. The certificate is valid till 05-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 03-07-2018 specifying import of 80Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide valid GMP certificate / inspection report of the contract manufacturer since the submitted GMP certificate has been expired.	The firm has submitted last inspection report dated 01/04/2019. The firm has maintained conformance to GMP compliance in manufacturing and QC operations.
2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Copies of the drug substance specifications and analytical procedures used for routine testing of drug substance by both drug product and drug substance manufacturer in the relevant sections as per guidance document for Form 5F.
4.	Provide details of the analytical method and concentrations in terms of mg/ml used to test the parameters in verification / validation studies of the drug substance. Further justify significant difference in peak areas value at same concentration during different tests like precision and accuracy/linearity.	The firm has submitted analytical method verification studies (including specificity, precision and accuracy etc) with the detail of concentrations of different dilutions used to test the parameters of required studies.
5.	The commercial invoice specifying ceftriaxone sodium sterile (USP) having batch number 3051805046 was cleared by AD (I&E) DRAP Lahore on 03-07-2018, while as per the certificate of analysis of raw material from Cunningham Pharmaceuticals, the material of same batch number was received on 05-01-2018 and was tested on 13-01-2018. Justification is required in this regard	*It was a typographical error. COA after correction is attached in 3.2.S.4.4.* *Receiving date: 07/07/2018* *Test date: 13/07/2018*
6.	Provide details of diluent which is used to perform compatibility studies of drug product.	Zee-inject (Water for injection (WFI) is used as a diluent for reconstitution of drug product. The reconstituted product is yellowish clear solution. COA of diluent is attached in Module 3 section

		3.2.P.1(c)Description of accompanying reconstitution diluent.
7.	Justify why the test of specificity is not performed during the verification / validation studies of the drug substance.	The firm has submitted analytical method verification report mentioning the results of the test for specificity parameter for analytical method verification studies for dug substance performed by drug product manufacturer.
8.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Certificate of analysis of reference standard actually used in the development of the applied product is provided.
9.	Provide details of sample solution 2 preparation i.e. exact volume of water required for initial constitution of the ceftriaxone for injection.	Detail of preparation of sample solution II is provided in the relevant section which is in-lined with USP for the applied product.
10.	Your analytical method for drug product specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria as per USP monograph, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.	Specifications of finished product has been revised with addition of acceptance criteria for assay as per USP monograph. Revised specifications are submitted which are in-lined with USP. The firm has stated that they have performed one test at the stage of drug substance analysis and the other test is performed at the drug product stage. "*as we are dealing with the toll manufacturing in order for better understanding on COA we opted the 90-115% assay specifications. However, we have revised the SOP along with the specifications and would update and align all the practices and documents".*
11.	Batch 180004 was manufactured on 01/2018 while stability was initiated on 12-05-2018. Justification is required in this regard. Batch 180019 was manufactured in May 2018 using drug substance lot number 3051805046 which was imported and cleared in July 2018. Justification is required in this regard. Batch 180004 was manufactured in January 2018 using drug substance lot number 3051805005 which was imported and cleared in July 2018. Justification is required in this regard.	*Batch # 180004 was released on 25-01-2018.But unfortunately; due to unavailability of packaging material (Unit cartons) the packing of this batch had faced some delay. That's why stability was initiated in 12-05-2018.* *Invoice for Batch # 180019 and Batch # 180004 was missing during file compilation. Import invoice is attached in Module 3 section 3.2.P.8.3. COA of drug substance is attached in Module 3 section 3.2.S.4.4.* *Invoice for Batch # 180019 and Batch # 180004 was missing during file compilation. Import invoice is attached in Module 3 section 3.2.P.8.3. COA of drug substance is attached in Module 3 section 3.2.S.4.4.*
12.	Justify why the test for water contents, constituted solution etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life.	*We were not performing these tests in our stability testing. Whereas these tests were part of our routine testing.* The firm has performed water content determination test and submitted that relevant data.
13.	Justify how the results of assay and pH of each batch is different at initial time point for accelerated and real time stability study. The results of assay test at initial time point for each batch is different in stability summary sheet and raw data sheets. Justification is required in this regard.	*Results of assay and pH at initial time point are not different. This was a typographical error. We are submitting revised summary sheets with correct value of assay and pH.*
14.	Provide 6 months stability study data of three batches along with HPLC chromatograms and raw data sheets in a proper sequence and with separators as per the guidelines of registration Board for further evaluation.	The firm has submitted 6 months stability data (including accelerated and real time) of three batches along with the relevant chromatograms, raw data sheets etc as per the guidelines of Registration Board.
15.	Stability study data of initial time point is not submitted for any batch along with stability studies.	The firm has submitted the required data alongwith raw data sheets and chromatograms.
16.	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board. • Lenzeu 30mg and 60mg Capsule (Dexlansoprazol) approved in 297th meeting. & Tazipera 45g injection approved in 316th meeting. • Copy of GMP certificate No. GD20180909 valid till 05/12/2023, M/s Zhuhai United Laboratories Co., Ltd., issued by CFDA.

	○ Documents for the procurement of API with approval from DRAP (in case of import). ○ Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. ○ Compliance Record of HPLC software 21CFR & audit trail reports on product testing. ○ Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Firm has submitted copy of commercial invoice cleared dated 28-05-2020 specifying import of 100Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP. • Raw data sheet sand chromatograms have been submitted by the firm. • The firm has submitted record of digital data logger for accelerated and real time stability studies in the relevant section. • Compliance record of HPLC & audit trails are submitted.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**

1074	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23858: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 08-06-2021
	The proposed proprietary name / brand name	**GENXONE Dry Powder Injection 1g (IV)**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……1g
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 1g Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance.

		Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	~~3051805046~~ ~~3051805005~~		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180003	180017	180018
Batch Size	8333 vials	8333 vials	8333 vials
Manufacturing Date	01-2018	05-2018	05-2018
Date of Initiation	01-2018	05-2018	05-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 06-10-2017 specifying import of 50Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide valid GMP certificate / inspection report of the contract manufacturer since the submitted GMP certificate has been expired.	The firm has submitted last inspection report dated 01/04/2019. The firm has maintained conformance to GMP compliance in manufacturing and QC operations.
2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.

3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Copies of the drug substance specifications and analytical procedures used for routine testing of drug substance by both drug product and drug substance manufacturer in the relevant sections as per guidance document for Form 5F.
4.	Provide details of the analytical method and concentrations in terms of mg/ml used to test the parameters in verification / validation studies of the drug substance. Further justify significant difference in peak areas value at same concentration during different tests like precision and accuracy/linearity.	The firm has submitted analytical method verification studies (including specificity, precision and accuracy etc) with the detail of concentrations of different dilutions used to test the parameters of required studies.
5.	Justify use of drug substance from Sinopharm Weiqida Pharmaceutical Co. Ltd for the applied strength, since you have claimed drug substance source from Zhuhai United Laboratories Co. Ltd in other strengths of the same product.	For manufacturing of already registered product Axitrim injeciton 1g IV of M/s Cunningham, the drug substance was purchase from M/s Sinopharm Weiqida Pharmaceuticals. Further demand for active material was placed but due to unavailability of active material from sinopharm we decided to change the manufacturer to Zhuhai United and developed our products using the material from Zhuhai united.
6.	Justify why the test of specificity is not performed during the verification / validation studies of the drug substance.	The firm has submitted analytical method verification report mentioning the results of the test for specificity parameter for analytical method verification studies for dug substance performed by drug product manufacturer.
7.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Certificate of analysis of reference standard actually used in the development of the applied product is provided.
8.	Provide details of sample solution 2 preparation i.e. exact volume of water required for initial constitution of the ceftriaxone for injection.	Detail of preparation of sample solution II is provided in the relevant section which is in-lined with USP for the applied product.
9.	Your analytical method for drug product specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria as per USP monograph, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.	Specifications of finished product has been revised with addition of acceptance criteria for assay as per USP monograph. Revised specifications are submitted which are in-lined with USP. The firm has stated that they have performed one test at the stage of drug substance analysis and the other test is performed at the drug product stage. "*as we are dealing with the toll manufacturing in order for better understanding on COA we opted the 90-115% assay specifications. However, we have revised the SOP along with the specifications and would update and align all the practices and documents".*
10.	Provide date of initiation and date of testing at each time point for every batch during stability studies.	Batch No.: 180003 initiated on 12/04/2018 Batch No.: 180017 initiated on 28/06/2018 Batch No.: 180018 initiated on 07/06/2018
11.	Justify why the test for water contents, constituted solution etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life.	*We were not performing these tests in our stability testing. Whereas these tests were part of our routine testing.* The firm has performed water content determination test and submitted that relevant data.
12.	Justify how the results of assay and pH of each batch is different at initial time point for accelerated and real time stability study. The results of assay test at initial time point for each batch is different in stability summary sheet and raw data sheets. Justification is required in this regard.	*Results of assay and pH at initial time point are not different. This was a typographical error. We are submitting revised summary sheets with correct value of assay and pH.*

13.	Provide 6 months stability study data of three batches along with HPLC chromatograms and raw data sheets in a proper sequence and with separators as per the guidelines of registration Board for further evaluation.	The firm has submitted 6 months stability data (including accelerated and real time) of three batches along with the relevant chromatograms, raw data sheets etc as per the guidelines of Registration Board.
14.	Stability study data of initial time point is not submitted for any batch along with stability studies.	The firm has submitted the required data alongwith raw data sheets and chromatograms.
15.	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. o Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board. • Lenzeu 30mg and 60mg Capsule (Dexlansoprazol) approved in 297th meeting. & Tazipera 45g injection approved in 316th meeting. • Copy of GMP certificate No. GD20180909 valid till 05/12/2023, M/s Zhuhai United Laboratories Co., Ltd., issued by CFDA. • Firm has submitted copy of commercial invoice cleared dated 28-05-2020 specifying import of 100Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP. • Raw data sheet sand chromatograms have been submitted by the firm. • The firm has submitted record of digital data logger for accelerated and real time stability studies in the relevant section. • Compliance record of HPLC & audit trails are submitted.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**

1075	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019

		based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23851: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 08-06-2021
	The proposed proprietary name / brand name	**GENXONE Dry Powder Injection 1g (IM)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……1g
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 1g Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	3051805046 3051805005		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180003	180017	180018
Batch Size	8333 vials	8333 vials	8333 vials
Manufacturing Date	01-2018	05-2018	05-2018
Date of Initiation	01-2018	05-2018	05-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (No. SX20180229) issued by CFDA China is submitted by the firm. The certificate is valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 06-10-2017 specifying import of 50Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP.

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide valid GMP certificate / inspection report of the contract manufacturer since the submitted GMP certificate has been expired.	The firm has submitted last inspection report dated 01/04/2019. The firm has maintained conformance to GMP compliance in manufacturing and QC operations.
2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Copies of the drug substance specifications and analytical procedures used for routine testing of drug substance by both drug product and drug substance manufacturer in the relevant sections as per guidance document for Form 5F.
4.	Provide details of the analytical method and concentrations in terms of mg/ml used to test the parameters in verification / validation studies of the drug substance. Further justify significant difference in peak areas value at same concentration during different tests like precision and accuracy/linearity.	The firm has submitted analytical method verification studies (including specificity, precision and accuracy etc) with the detail of concentrations of different dilutions used to test the parameters of required studies.
5.	Justify use of drug substance from Sinopharm Weiqida Pharmaceutical Co. Ltd for the applied strength, since you have claimed drug substance source from Zhuhai United Laboratories Co. Ltd in other strengths of the same product.	For manufacturing of already registered product Axitrim injeciton 1g IV of M/s Cunningham, the drug substance was purchase from M/s Sinopharm Weiqida Pharmaceuticals. Further demand for active material was placed but due to unavailability of active material from sinopharm we decided to change the manufacturer to Zhuhai United and developed our products using the material from Zhuhai united.
6.	Justify why the test of specificity is not performed during the verification / validation studies of the drug substance.	The firm has submitted analytical method verification report mentioning the results of the test for specificity parameter for analytical method verification studies for dug substance performed by drug product manufacturer.
7.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	The firm ha ssubmitted COA of the relevant batch of drug substance which was used in product development from drug product and drug substance manfuactruer.
8.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Certificate of analysis of reference standard actually used in the development of the applied product is provided.
9.	You have specified that diluent for this product is 2ml lignocaine injection while the innovator's product recommend use of 2.1 or 3.6ml of diluent.	The firm has stated that the volume of diluent that is lignocaine was exactly the same as used by the innovator.
10.	Justify how compatibility studies of IV injection can be used for ceftriaxone IM injection as well	The firm has submitted compatibility studies of the product with the recommended diluent that is Lignocaine for IM injection.
11.	Justify how single BMR can be used for a single batch of two separately registered products like ceftriaxone 1g IM and 1g IV Injection.	The firm has submitted complete batch manufacturing record for the applied formulation and has stated that the BMD of IV injection was placed in the dossier, mistakenly.

12.	Submit product development and stability study data of 3 batches of ceftriaxone 1g IM injection for further evaluation.	The firm has submitted product development along with the stability study data including accelerated and real time stability studies of 3 batches along with the relevant chromatograms and raw data sheets.
13.	Provide details of sample solution 2 preparation i.e. exact volume of water required for initial constitution of the ceftriaxone for injection.	Detail of preparation of sample solution II is provided in the relevant section which is in-lined with USP for the applied product.
14.	Your analytical method for drug product specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria as per USP monograph, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.	Specifications of finished product has been revised with addition of acceptance criteria for assay as per USP monograph. Revised specifications are submitted which are in-lined with USP. The firm has stated that they have performed one test at the stage of drug substance analysis and the other test is performed at the drug product stage. "*as we are dealing with the toll manufacturing in order for better understanding on COA we opted the 90-115% assay specifications. However, we have revised the SOP along with the specifications and would update and align all the practices and documents".*
15.	Justify why the test for water contents, constituted solution etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life.	*We were not performing these tests in our stability testing. Whereas these tests were part of our routine testing.* The firm has performed water content determination test and submitted that relevant data.
16.	Provide 6 months stability study data of three batches along with HPLC chromatograms and raw data sheets in a proper sequence and with separators as per the guidelines of registration Board for further evaluation.	The firm has submitted 6 months stability data (including accelerated and real time) of three batches along with the relevant chromatograms, raw data sheets etc as per the guidelines of Registration Board.
17.	Stability study data of initial time point is not submitted for any batch along with stability studies.	The firm has submitted the required data alongwith raw data sheets and chromatograms.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**

1076	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals dated 19-04-2019 based on the inspection dated 01-04-2019. The certificate was valid till 01-04-2022.

		The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License to M/s Cunningham Pharmaceuticals dated 13-06-2016. The letter specifies dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23852: 31-08-2021
	Details of fee submitted	PKR 75,000/-: 08-06-2021
	The proposed proprietary name / brand name	**GENXONE Dry Powder Injection 2g (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……2g
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Oxidil 2g Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Zhuhai United Laboratories Co. Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District Zhuhai Guangdong P.R China.		
API Lot No.	3052004003		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T01	T01
Batch Size	100 vials	100 vials	100 vials
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. GD20180909) issued by CFDA China. The certificate is valid till 05-12-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 28-05-2020 specifying import of 100Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide valid GMP certificate / inspection report of the contract manufacturer since the submitted GMP certificate has been expired.	The firm has submitted last inspection report dated 01/04/2019. The firm has maintained conformance to GMP compliance in manufacturing and QC operations.
2.	Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.	Module I is submitted as per CTD guidance document.
3.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Copies of the drug substance specifications and analytical procedures used for routine testing of drug substance by both drug product and drug substance manufacturer in the relevant sections as per guidance document for Form 5F.
4.	Provide details of the analytical method and concentrations in terms of mg/ml used to test the parameters in verification / validation studies of the drug substance. Further justify significant difference in peak areas value at same concentration during different tests like precision and accuracy/linearity.	The firm has submitted analytical method verification studies (including specificity, precision and accuracy etc) with the detail of concentrations of different dilutions used to test the parameters of required studies.
5.	Justify why the test of specificity is not performed during the verification / validation studies of the drug substance.	The firm has submitted analytical method verification report mentioning the results of the test for specificity parameter for analytical method verification studies for dug substance performed by drug product manufacturer.
6.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Certificate of analysis of reference standard actually used in the development of the applied product is provided.
7.	You have mentioned that 10ml water for injection is used as diluent for the applied product while the innovator's product has recommended use of much high volume of diluent. Justification is required in this regard.	The recommended volume for diluent (Water for Injection) for 2g injection is 20mL as mentioned in product monograph of Rocephin (IV)2g. Compatibility studies of diluent that is water for injection 20mL with the finished product has been performed and submitted.
8.	Justify why pharmaceutical equivalence studies are conducted against comparator product instead of using innovator or reference product.	The firm has stated that Pharmaceutical equivalence is performed against Oxidil 2g injection mfg by M/s Sami Pharma. The innovator's product is not avalaible in
9.	Provide details of the diluent which is used to perform compatibility studies of the drug product.	Water for injection 20mL is used as diluent for reconstitution of drug product. The reconstituted product is yellowish clear solution. The firm has submitted compatibility studies of diluent with the rug product.
10.	Provide details of sample solution 2 preparation i.e. exact volume of water required for initial constitution of the ceftriaxone for injection.	Detail of preparation of sample solution II is provided in the relevant section which is in-lined with USP for the applied product.

11.	Your analytical method for drug product specifies two different sample solutions as well as two different analysis, calculation formula and acceptance criteria as per USP monograph, while your specifications does not specify two different tests and acceptance criteria for assay and you have released your batches with only 1 type of assay results. Justify why your specifications, analytical method and practices of batch release are not aligned with USP monograph recommendations.	Specifications of finished product has been revised with addition of acceptance criteria for assay as per USP monograph. Revised specifications are submitted which are in-lined with USP. The firm has stated that they have performed one test at the stage of drug substance analysis and the other test is performed at the drug product stage. "*as we are dealing with the toll manufacturing in order for better understanding on COA we opted the 90-115% assay specifications. However, we have revised the SOP along with the specifications and would update and align all the practices and documents".*
12.	Provide 6 months stability study data of three batches along with HPLC chromatograms and raw data sheets in a proper sequence and with separators as per the guidelines of registration Board for further evaluation.	The firm has submitted 6 months stability data (including accelerated and real time) of three batches along with the relevant chromatograms, raw data sheets etc as per the guidelines of Registration Board.
13.	Submit stability study data of 3 commercial batches manufactured by the drug product manufacturer as per the decision of 312th meeting of Registration Board wherein the Board decided that the permission for contract manufacturing shall be granted on the basis of stability study data of commercial batches.	The firm has submitted stability study data of 3 batches as well. Batch size: 1000 vials Mfg date: 11/2020 Date of initiation of stability studies: 05/12/2020 Batches: T01, T02, T03 Batch size: 1000 vials
14.	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. o Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board. • Lenzeu 30mg and 60mg Capsule (Dexlansoprazol) approved in 297th meeting. & Tazipera 45g injection approved in 316th meeting. • Copy of GMP certificate No. GD20180909 valid till 05/12/2023, M/s Zhuhai United Laboratories Co., Ltd., issued by CFDA. • Firm has submitted copy of commercial invoice cleared dated 28-05-2020 specifying import of 100Kg ceftriaxone sodium sterile (USP). The invoice is cleared by AD (I&E) DRAP. • Raw data sheet sand chromatograms have been submitted by the firm. • The firm has submitted record of digital data logger for accelerated and real time stability studies in the relevant section. • Compliance record of HPLC & audit trails are submitted.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer shall submit testing record of recently manufactured commercial batch as per USP monograph before issuance of Registration Letter.**

1077	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Z-Jans Pharmaceuticals Pvt. Ltd. 148-A Industrial area Hayatabad Peshawar**
	Name, address of Manufacturing site.	M/s Z-Jans Pharmaceuticals Pvt. Ltd. 148-A Industrial area Hayatabad Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 07-08-2018 issued on the basis of inspection dated 02-08-2018. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 29-01-2009 specifying dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23008: 24-08-2021
	Details of fee submitted	PKR 20,000/-: 16-10-2020
	The proposed proprietary name / brand name	**ZOCLAN 250mg Injection ~~IV~~**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……250mg
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Oxidil 250mg Injection IM.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C-FML 41K	C-FML 42K	C-FML 43K
Batch Size	50,000 vials	50,000 vials	50,000 vials
Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	16-08-2017	23-08-2017	29-08-2017
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

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

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Specify whether your application is for IV or IM use.
- Submi module 2 and module 3 as per the format and data requirements as specified in the CTD guidance document approved by Registration Board.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.
- Submit COA of relevant batch of drug substance from API manufacturer as well as drug product manufacturer in section 3.2.S.4.4 which is actually used for manufacturing of three stability batches.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance and drug product.
- Submit details of the manufacturer of the comparator product Recephin Injection Batch No. B0063 against which pharmaceutical eqivalence studies were conducted.
- Justify how the average weight of filled vials of the comparator product as well as your product is 272mg and the assay is 105%.
- Submit compatibility studies in section 3.2.P.2.6.
- Submit process validation protocols as per the requirements of CTD guidance document.
- Justify the specifications of the drug product which are not as per USP monograph, since the test for constituted solution, bacterial endotoxin test, particulate matter in injection, crystallinity, pH, water determination, assay having acceptance criteria (NLT 776 µg/mg of ceftriaxone) and impurities.
- Justify your analytical method for assay test of drug product which is entirely different from that of USP in terms of mobile phase composition, standard and sample preparation, and chromatographic conditions including UV wavelength, flow rate, injection volume etc.
- Justify the assay test of drug product using UV method in your specifications since no such test exist in USP monograph.
- Provide verification studies of the analytical method of drug roduct in section 3.2.P.5.4 in the light of ICH guidelines.
- Justify the stability testing of the product in which assay is determined using UV method against the recommendations of USP.
- Provide Batch Manufacturing Record of three stability batches for which stability study data is submitted.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

	○ Documents for the procurement of API with approval from DRAP (in case of import). ○ Compliance Record of HPLC software 21CFR & audit trail reports on product testing. ○ Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1078	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Z-Jans Pharmaceuticals Pvt. Ltd. 148-A Industrial area Hayatabad Peshawar**
	Name, address of Manufacturing site.	M/s Z-Jans Pharmaceuticals Pvt. Ltd. 148-A Industrial area Hayatabad Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 07-08-2018 issued on the basis of inspection dated 02-08-2018. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additional section dated 29-01-2009 specifying dry powder injection (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23009: 24-08-2021
	Details of fee submitted	PKR 20,000/-: 16-10-2020
	The proposed proprietary name / brand name	**ZOCLAN 500mg Injection ~~IV~~**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container

		closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 500mg Injection IM.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	~~Q011910019~~		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C-FML 31K	C-FML 32K	C-FML 31K
Batch Size	50,000 vials	50,000 vials	50,000 vials
Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	31-07-2017	08-08-2017	11-08-2017

No. of Batches	03	
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Specify whether your application is for IV or IM use.
- Submi module 2 and module 3 as per the format and data requirements as specified in the CTD guidance document approved by Registration Board.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3.
- Submit COA of relevant batch of drug substance from API manufacturer as well as drug product manufacturer in section 3.2.S.4.4 which is actually used for manufacturing of three stability batches.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance and drug product.
- Submit details of the manufacturer of the comparator product Recephin Injection Batch No. B0063 against which pharmaceutical eqivalence studies were conducted. Further justify how same batch number of the comparator product is used for 250mg and 500mg strength.
- Justify how the average weight of filled vials of the comparator product as well as your product is 550mg and the assay is 105%.
- Submit compatibility studies in section 3.2.P.2.6.
- Submit process validation protocols as per the requirements of CTD guidance document.
- Justify the specifications of the drug product which are not as per USP monograph, since the test for constituted solution, bacterial endotoxin test, particulate matter in injection, crystallinity, pH, water determination, assay having acceptance criteria (NLT 776 µg/mg of ceftriaxone) and impurities.
- Justify your analytical method for assay test of drug product which is entirely different from that of USP in terms of mobile phase composition, standard and sample preparation, and chromatographic conditions including UV wavelength, flow rate, injection volume etc.
- Justify the assay test of drug product using UV method in your specifications since no such test exist in USP monograph.
- Provide verification studies of the analytical method of drug roduct in section 3.2.P.5.4 in the light of ICH guidelines.
- Justify the stability testing of the product in which assay is determined using UV method against the recommendations of USP.

- Provide Batch Manufacturing Record of three stability batches for which stability study data is submitted.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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

1079	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories, Plot # 121 Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-12-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Lyophilized vial (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Lyophilized vial (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Lyophilized vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19156: 08-07-2021
	Details of fee submitted	PKR 50,000/-: 26-01-2021
	The proposed proprietary name / brand name	**ZOLARD Injection 30mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Lansoprazole……30mg
	Pharmaceutical form of applied drug	Almost white coloured lyophilized hygroscopic powder contained in glass vial
	Pharmacotherapeutic Group of (API)	PPI

	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lansoprazole Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Qpro injection by Bosch Pharma
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Selanz 30mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		
Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.	

API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document. Furthermore, it is also pertinent to mention that the drug product testing has been carried out using specifications which are not in line with the recommendations of the general monographs of the official pharmacopoeia and the analytical method of the assay test is based on UV method contrary to the method of analysis of the drug substance manufacturer and innovator's product.

Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board and also justifying the specifications of the drug product so that further evaluation of your application could be carried out.

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

1080	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Gray's Pharmaceuticals. Plot No. 2, Street No. N-3, RCCI Rawat Rawalpindi.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-12-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Lyophilized vial (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Lyophilized vial (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Lyophilized vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18913: 06-07-2021
	Details of fee submitted	PKR 50,000/-: 29-12-2020
	The proposed proprietary name / brand name	**LADAZOLE Injection 30mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Lansoprazole……30mg
	Pharmaceutical form of applied drug	Almost white coloured lyophilized hygroscopic powder contained in glass vial
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	In house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lansoprazole Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Qpro injection by Bosch Pharma
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Selanz 30mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.		
API Lot No.	ALAN 18001		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	L-213	L-233	L-252
Batch Size	9500 Packs	9500 Packs	9500 Packs
Manufacturing Date	08-2019	08-2019	08-2019
Date of Initiation	17-08-2019	17-08-2019	17-08-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document. Furthermore, it is also pertinent to mention that the drug product testing has been carried out using specifications which are not in line with the recommendations of the general monographs of the official pharmacopoeia and the analytical method of the assay test is based on UV method contrary to the method of analysis of the drug substance manufacturer and innovator's product.

Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board and also justifying the specifications of the drug product so that further evaluation of your application could be carried out.

Firm has now submitted application as per guidance document. However, the following observations are still not addressed.

- Verification studies of the analytical method of drug substance since the API used is non-lyophilized powder.
- pH of reference product is 9 – 10.5 while the limit set by firm is 9 – 12 and results are above 11.0
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

1081	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-06-2019.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection

		dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section. Firm has also submitted copy of letter for grant of additional section dated 27-02-2011 specifying dry powder injection (cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19153: 08-07-2021
	Details of fee submitted	PKR 50,000/-: 15-03-2021
	The proposed proprietary name / brand name	**FORLAM 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftazidime……250mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Nivador injection by Sami Pharma
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Fortum 250mg Injection of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.		
API Lot No.			
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VP-1454	VP-1546	VP-1633
Batch Size	12,000 vials	10,000 vials	5,000 vials
Manufacturing Date	01-2018	04-2018	07-2018
Date of Initiation	19-03-2018	18-06-2018	17-09-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170590) issued by CFDA China dated 31-07-2017. The GMP certificate is valid till 30-07-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

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

Evaluation by PEC:

The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document for various modules, sections and sub sections majorly including complete module 1, section 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.4, 3.2.S.5, 3.2.P.2.2.1, 3.2.P.2.6, 3.2.P.3.5, 3.2.P.5.1, 3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.4, 3.2.P.6 and 3.2.P.8. Furthermore, it is also pertinent to mention that the drug product manufacturer has submitted COA of drug substance imported in 2021 and released on 13-03-2021 and provided batch release certificates of 3 batches of drug product released on 19-05-2021, 15-01-2021 and 22-12-2020 and submitted stability study data of 3 batches of drug product 19-03-2018, 18-06-2018 and 17-09-2018 instead of submitting data of same batches as per the guidance document. Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board and also justifying the following additional observations so that further evaluation of your application could be carried out.

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- You have submitted Innovator's specification in module 1 while the product monograph is available in USP, revise the specifications along with submission of requisite fee.
- You have submitted label claim that each vial contains ceftazidime as sodium 250mg while the innovator product contains ceftazidime pentahydrate.
- The specifications of the drug substance manufacturer is different from USP in terms of limit of loss on drying as well as chromatographic conditions (including column specifications, wavelength, flow rate, mobile phase etc). Justify how this material can be used to develop commercial batches of a product which is registered with USP specifications.
- M/s Biolabs have released a batch of drug substance (Batch No. 1045AJ81JD) on 13-03-2021 in which loss on drying was 13.45% while USP specifies that the limit of LOD is NMT 12.5%. Justify how this drug substance was released for commercial use to manufacture batches of the drug product registered with USP specifications.
- You have specified in section 3.2.P.1 that filled weight per vial is 250mg which is contrary to that of the innovator product.
- Your product development and pharmaceutical equivalence studies does not include complete testing as recommended by innovator product or by USP.
- Compatibility studies of your product shows that pH after reconstitution is from 3 to 4 which is different from that of USP recommendations.
- Your drug substance specifications are different from that of drug substance manufacturer as well as USP without any scientific rationale.
- Your process validation report performed on commercial batches have specified that weight variation of the filled vials is approximately 250mg. Justify how 250mg powder per vial containing sodium carbonate as well as 13.5% water can have 250mg of ceftazidime base as well.
- Your drug product specifications are not as per USP since many tests recommended by USP are not performed by the product manufacturer even for the release of commercial batches in the market.
- The drug product manufacturer have not provided complete method of analysis of the drug product although it is manufacturing commercial batches of the said product.
- Justify why contents of sodium carbonate is not performed in the drug product also provide evidence of atomic absorption to justify that you have necessary equipment to carry out the product testing.
- The limit of Bacterial endotoxin test of the drug product manufacturer is different from USP pharmacopoeia.

- Provide evidence of import of Ceftazidime, Delta-3-Isomer RS which is used in the analysis of drug product.
- The drug product method of analysis specifies that a resolution solution containing Delta-3-Isomer RS is added in the sample solution, while no peak is observed in the chromatograms. Justify how your method of analysis can be considered accurate and reliable.
- Your analytical method verification studies are not performed in the light of ICH guidelines, furthermore the analysis of results is also not performed as per ICH recommendations. Justify how you have been testing commercial batches of the drug product without having a verified method of analysis in which the resolution solution peak is also not observed in the chromatograms.

Response by the firm:
The firm has submitted stability study data of 3 newly manufactured batches of drug product without addressing the observations mentioned in the letter of shortcoming.

Batch No.	VP-339	VP-340	VP-361
Batch Size	15384 Packs	15384 vials	5,000 vials
Manufacturing Date	12-2019	12-2019	12-2019
Date of Initiation	26-12-2019	26-12-2019	26-12-2019

- The analysis performed in the newly submitted data is still not as per USP monograph in terms of relative retention time between ceftazidime and Delta-3-Isomer and the calculation of results of assay.

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

1082	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-06-2019.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section. Firm has also submitted copy of letter for grant of additional section dated 27-02-2011 specifying dry powder injection (cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 19154: 08-07-2021
	Details of fee submitted	PKR 50,000/-: 15-03-2021
	The proposed proprietary name / brand name	**FORLAM 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftazidime……500mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Nivador injection by Sami Pharma
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Fortum 500mg Injection of GSK.

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

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.		
API Lot No.	~~0046L81F~~		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VP-1453	VP-1545	VP-1632
Batch Size	6,000 vials	10,000 vials	5,000 vials
Manufacturing Date	01-2018	04-2018	07-2018
Date of Initiation	19-03-2018	18-06-2018	17-09-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170590) issued by CFDA China dated 31-07-2017. The GMP certificate is valid till 30-07-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document for various modules, sections and sub sections majorly including complete module 1, section 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.4, 3.2.S.5, 3.2.P.2.2.1, 3.2.P.2.6, 3.2.P.3.5, 3.2.P.5.1, 3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.4, 3.2.P.6 and 3.2.P.8. Furthermore, it is also pertinent to mention that the drug product manufacturer has submitted COA of drug substance imported in 2021 and released on 13-03-2021 and provided batch release certificates of 3 batches of drug product released on 05-10-2020, 15-12-2020 and 02-05-2021 and submitted stability study data of 3 batches of drug product released on 19-03-2018, 18-06-2018 and 17-09-2018 instead of submitting data of same batches as per the guidance document. Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration

Board and also justifying the following additional observations so that further evaluation of your application could be carried out.

- Submit differential fee for the registration of applied product as per SRO No. F.7-11/2012-B&A/DRA.
- You have submitted Innovator's specification in module 1 while the product monograph is available in USP, revise the specifications along with submission of requisite fee.
- You have submitted label claim that each vial contains ceftazidime as sodium 250mg while the innovator product contains ceftazidime pentahydrate.
- The specifications of the drug substance manufacturer is different from USP in terms of limit of loss on drying as well as chromatographic conditions (including column specifications, wavelength, flow rate, mobile phase etc). Justify how this material can be used to develop commercial batches of a product which is registered with USP specifications.
- M/s Biolabs have released a batch of drug substance (Batch No. 1045AJ81JD) on 13-03-2021 in which loss on drying was 13.45% while USP specifies that the limit of LOD is NMT 12.5%. Justify how this drug substance was released for commercial use to manufacture batches of the drug product registered with USP specifications.
- Justify the assay result of ceftazidime pentahydrate 69.33% as per your test report dated 13-03-2021.
- You have specified in section 3.2.P.1 that filled weight per vial is 500mg which is contrary to that of the innovator product.
- Your product development and pharmaceutical equivalence studies does not include complete testing as recommended by innovator product or by USP.
- Your drug substance specifications are different from that of drug substance manufacturer as well as USP without any scientific rationale.
- Your process validation report performed on commercial batches have specified that weight variation of the filled vials is approximately 500mg (509-512mg). Justify how 500mg powder per vial containing sodium carbonate as well as 13.5% water can have 500mg of ceftazidime base as well.
- Your drug product specifications are not as per USP since many tests recommended by USP are not performed by the product manufacturer even for the release of commercial batches in the market.
- The drug product manufacturer have not provided complete method of analysis of the drug product although it is manufacturing commercial batches of the said product.
- Justify why contents of sodium carbonate is not performed in the drug product also provide evidence of atomic absorption to justify that you have necessary equipment to carry out the product testing.
- The limit of Bacterial endotoxin test of the drug product manufacturer is different from USP pharmacopoeia.
- Provide evidence of import of Ceftazidime, Delta-3-Isomer RS which is used in the analysis of drug product.
- The drug product method of analysis specifies that a resolution solution containing Delta-3-Isomer RS is added in the sample solution, while no peak is observed in the chromatograms. Justify how your method of analysis can be considered accurate and reliable.
- Your analytical method verification studies are not performed in the light of ICH guidelines, furthermore the analysis of results is also not performed as per ICH recommendations. Justify how you have been testing commercial batches of the drug product without having a verified method of analysis in which the resolution solution peak is also not observed in the chromatograms.

Response by the firm:

The firm has submitted stability study data of 3 newly manufactured batches of drug product without addressing the observations mentioned in the letter of shortcoming.

Batch No.	VP-267	VP-264	VP-263
Batch Size	7692 Packs	7692 vials	7692 vials
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	28-10-2019	28-10-2019	28-10-2019

- The analysis performed in the newly submitted data is still not as per USP monograph in terms of relative retention time between ceftazidime and Delta-3-Isomer and the calculation of results of assay.

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

1083	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 15-06-2019.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies dry powder injection (cephalosporin) section. Firm has also submitted copy of letter for grant of additional section dated 27-02-2011 specifying dry powder injection (cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18912: 06-07-2021
	Details of fee submitted	PKR 50,000/-: 15-03-2021
	The proposed proprietary name / brand name	**FORLAM 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftazidime……1g
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftazidime Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Nivador injection by Sami Pharma
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Fortum 1g Injection of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.		
API Lot No.	~~0046L81F~~		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VP-260	VP-437	VP-1478
Batch Size	7500 vials	3942 vials	7,000 vials
Manufacturing Date	09-2019	02-2020	02-2018

Date of Initiation	16-09-2019	16-03-2020	19-03-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170590) issued by CFDA China dated 31-07-2017. The GMP certificate is valid till 30-07-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The application for contract manufacturing from M/s Bio-Labs (Pvt) Ltd. Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document for various modules, sections and sub sections majorly including complete module 1, section 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.4, 3.2.S.5, 3.2.P.2.2.1, 3.2.P.2.6, 3.2.P.3.5, 3.2.P.5.1, 3.2.P.5.2, 3.2.P.5.3, 3.2.P.5.4, 3.2.P.6 and 3.2.P.8. Furthermore, it is also pertinent to mention that the drug product manufacturer has submitted COA of drug substance imported in 2021 and released on 13-03-2021 and provided batch release certificates of 3 batches of drug product released on 05-05-2021, 16-01-2021 and 29-06-2020 and submitted stability study data of 3 batches of drug product released on 16-09-2019, 16-03-2020 and 19-03-2018 instead of submitting data of same batches as per the guidance document. Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board and also justifying the following additional observations so that further evaluation of your application could be carried out.

- Submit differential fee for the registration of applied product as per SRO No. F.7-11/2012-B&A/DRA.
- You have submitted Innovator's specification in module 1 while the product monograph is available in USP, revise the specifications along with submission of requisite fee.
- You have submitted label claim that each vial contains ceftazidime as sodium 250mg while the innovator product contains ceftazidime pentahydrate.
- The specifications of the drug substance manufacturer is different from USP in terms of limit of loss on drying as well as chromatographic conditions (including column specifications, wavelength, flow rate, mobile phase etc). Justify how this material can be used to develop commercial batches of a product which is registered with USP specifications.
- M/s Biolabs have released a batch of drug substance (Batch No. 1045AJ81JD) on 13-03-2021 in which loss on drying was 13.45% while USP specifies that the limit of LOD is NMT 12.5%. Justify how this drug substance was released for commercial use to manufacture batches of the drug product registered with USP specifications.
- Justify the assay result of ceftazidime pentahydrate 69.33% as per your test report dated 13-03-2021.
- You have specified in section 3.2.P.1 that filled weight per vial is 1g which is contrary to that of the innovator product.
- Your product development and pharmaceutical equivalence studies does not include complete testing as recommended by innovator product or by USP.
- Your drug substance specifications are different from that of drug substance manufacturer as well as USP without any scientific rationale.

- Your process validation report performed on commercial batches have specified that weight variation of the filled vials is approximately 1000mg (1005-1011mg). Justify how 1000mg powder per vial containing sodium carbonate as well as 13.5% water can have 1000mg of ceftazidime base as well.
- Your drug product specifications are not as per USP since many tests recommended by USP are not performed by the product manufacturer even for the release of commercial batches in the market.
- The drug product manufacturer have not provided complete method of analysis of the drug product although it is manufacturing commercial batches of the said product.
- Justify why contents of sodium carbonate is not performed in the drug product also provide evidence of atomic absorption to justify that you have necessary equipment to carry out the product testing.
- The limit of Bacterial endotoxin test of the drug product manufacturer is different from USP pharmacopoeia.
- Provide evidence of import of Ceftazidime, Delta-3-Isomer RS which is used in the analysis of drug product.
- The drug product method of analysis specifies that a resolution solution containing Delta-3-Isomer RS is added in the sample solution, while no peak is observed in the chromatograms. Justify how your method of analysis can be considered accurate and reliable.
- Your analytical method verification studies are not performed in the light of ICH guidelines, furthermore the analysis of results is also not performed as per ICH recommendations. Justify how you have been testing commercial batches of the drug product without having a verified method of analysis in which the resolution solution peak is also not observed in the chromatograms.

Response by the firm:
The firm has submitted stability study data of 3 newly manufactured batches of drug product without addressing the observations mentioned in the letter of shortcoming.

Batch No.	VP-257	VP-258	VP-260
Batch Size	3846 Packs	3846 Packs	3846 Packs
Manufacturing Date	09-2019	09-2019	09-2019
Date of Initiation	26-09-2019	26-09-2019	26-09-2019

- The analysis performed in the newly submitted data is still not as per USP monograph in terms of relative retention time between ceftazidime and Delta-3-Isomer and the calculation of results of assay.

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

1084	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Reliance Pharma, Plot # 8, Street No. S-8, RCCI, Industrial Estate, Rawat Islamabad.**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd. Plot No. 204-205, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Copy of agreement for contract manufacturing of pharmaceutical products between contract giver and acceptor dated 25-02-2019 is submitted.
	GMP status of the firm	**Global pharmaceuticals:** 11 & 24-10-2018: On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000417 of M/s Global Pharmaceuticals Islamabad dated 03-02-2016 specifying reallocation of dry powder injection (carbapenem) section is place of withdrawn Biotech section (BSF)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1984: 15-07-2021
	Details of fee submitted	PKR 75,000/-: 28-06-2021
	The proposed proprietary name / brand name	**TAVIZEM 200mg/5ml suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	Off white powder filled in amber colored glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefiget 200mg/5ml dry suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.		
API Lot No.	18CF10062 18CF10068 18CF101233		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18D145	18L054	18G104
Batch Size	5000 bottle	5000 bottle	5000 bottle
Manufacturing Date	04-2018	11-2018	07-2018
Date of Initiation	18-04-2018	07-11-2018	05-07-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm

1.	Submit GMP certificate / GMP inspection report of the drug product manufacturer within last three years.	Firm has submitted GMP certificate issued on the basis of inspection dated 03-01-2022.
2.	Submit evidence of approval of requisite manufacturing facility / section of the drug product manufacturer approved from Licensing Division DRAP.	The submitted GMP certificate specifies dry powder suspension (Cephalosporin) section.
3.	Submit module 1 as per CTD guidance document without referring to annexures.	Firm has submitted module 1 as per guidance document.
4.	Submit label claim as per the innovator product along with submission of fee for revision of label claim.	Firm has submitted label claim.
5.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Specifications of drug substance from API manufacturer and product manufacturer is submitted by the firm.
6.	Justify how the drug substance specification complies both USP as well as BP specifications.	As few tests were common in USP and BP therefore drug substance manufacturer mentioned both in CoA but we are following USP specification. Procedures as per USP are attached
7.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*	Firm has submitted verification of analytical procedure of drug substance.
8.	Submit COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted COA of reference working standard
9.	Submit stability study data of the drug substance (cefixime trihydrate in micronized form) from the drug substance manufacturer as per zone IV-A conditions.	Firm has submitted stability data of API
10.	Justify why your formulation is qualitatively different from that of innovator's product.	As per function of excipients, we are following the innovator formulation. No other ingredient is changed except the Thickening agent Xanthan Gum is replaced with Carboxy methylcellulose Sodium. Carboxy methylcellulose Sodium is synthetically prepared thickening agent purer as compare to Xanthan gum and has computability with cefixime.
11.	Justify how 1383.1mg of cefixime trihydrate is equivalent to 6 doses after reconstitution each having 200mg of cefixime base.	Yes the 1383mg of cefixime Trihydrate is equivalent to 06 doses of 200mg cefixime. Molecular weight of cefixime Trihydrate=507.50 Molecular weight of cefixime =453.46 %age purity of cefixime= (453.46/507.5)*100=89.35% (when 100% cefixime is present in cefixime Trihydrate), but USP states that: - Cefixime contains the equivalent of not less than 950ug (95%) and not more 1030ug (103%) of cefixime per mg, calculated on anhydrous basis. So average content of cefixime will be =(95+103)/2=99% Considering the average purity of cefixime in cefixime Trihydrate, then 89.35*(99/100)= 88.46% For 06 doses of 200mg/5mlcefixime suspension:- Cefixime required will be = 1200mg/Vial

		1200mg cefiximewill be equivalent to =(100/88.46)*1200=1355.438mg/Vial 2% overage was in practice due to production losses. So the adopted fill weight= 1382.54 Note :- this 2% overage is removed from the formulation now.
12.	Justify how your product is equivalent to the innovator's product since the innovator's product is available in 50ml, 75ml and 100ml bottle delivering 10, 15 and 20 doses while your product is available in 30ml bottle which can deliver 6 doses.	All product registered in Pakistan for cefixime DS Suspension (e.g. Cefspan DS Suspension brand leader in Pakistan provide 30ml Pack size for 06 doses) is also available in 30ml Pack size, those also delivers 6 doses.
13.	Justify how you are reconstituting your product with 20ml water since the innovator product use 34ml water to reconstitute for 50ml bottle.	Reconstitution volume doesn't have any effect on the quality of Dry suspension, but for the sake comparison, we suppose:- If innovator uses 34ml for 50ml reconstitution, then for 30ml reconstitution we required =20.4ml, which is approximately equal to 20ml. As data of innovator formulation in quantitative form is not available, so this kind of change does come in generic development. Secondly as reference "Cefspan DS Suspension" the brand leader in Pakistan, is also reconstituting its product with 20ml water.
14.	Justify why you have performed pharmaceutical equivalence studies against Cefiget suspension instead of performing studies against the innovator / reference product.	We have performed the pharmaceutical equivalence against the competitor product, which is allowed by DRAP.
15.	Justify your pharmaceutical equivalence studies in which only assay and identification test has been performed. Justify how you can declare your product as pharmaceutically equivalent just on the basis of two tests.	Complete testing as per USP and innovator has been performed
16.	Justify why comparative dissolution profile / drug release studies are not performed for your product since USFDA has recommended such studies for cefixime suspension.	Dissolution test in the innovator recommended media is attached 8 for you concern. Note:-We have provided you the commercial batches data as per USP monograph, which doesn't mention the dissolution as quality parameter. Secondly the SMPC of innovator product only give the dissolution in one media (buffer pH 7.4), and mention it worthless quality control tool. SMPC clearly states that The current USP monograph for cefixime for oral suspension doesn't include dissolution. Itshould be noted that under established test conditions, all cefixime suspensions are rapidly dissolved (greater than settled limit (75%) in first 10minutes; dissolution is complete within 30minutes). The established test therefore appears to have limited value as quality control tool.
17.	Provide detailed method of analysis of the drug product in section 3.2.P.5.2 instead of providing USP monograph only.	Firm has submitted complete method of analysis of drug product.
18.	Provide detailed analytical method verification studies along with interpretation of each test in the light of ICH guidelines. Further also provide exact concentration of each solution tested in each test of the verification studies.	Firm has submitted detailed analytical method verification studies of drug product.
19.	Provide COA of 3 batches of drug product in section 3.2.P.5.4 for which stability study data is submitted in section 3.2.P.8.3.	Frm has submitted COA of three batches of drug product.
20.	Provide COA of reference standard which is actually used in the analysis of drug product.	Firm has submitted COA of working standard.
21.	Scientific justification for using only 3 chromatograms of the standard solution for HPLC testing while USP General chapter <621>	6 injections of standard solution run for system suitability confirmation in each assay and then 3 more

	recommends that five replicates of standard solution should be used for system suitability studies.	standards run in order to calculate results. System suitability RSD Sheets are attached as annexure 12.
22.	Provide reference of previous approval of applications with stability study data of the firm (if any), instead of mentioning not applicable.	Not submitted
23.	Provide documents for the procurement of API including commercial invoice of the relevant batch of drug substance used in the manufacturing of 3 batches for which stability study data is submitted.	Firm has submitted invoice of different batches of API
24.	Provide stability study data of 3 batches of the drug product in section 3.2.P.8.3 as per the 6 points checklist approved by Registration Board in CTD guidance document along with submission of stability study data of each batch in proper sequence i.e. analytical report, raw data sheet and chromatograms of standard and sample preparation at each time point so that further evaluation of the data could be carried out.	Submitted by the firm

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer shall submit data of product testing of recently manufactured commercial batches as per USP before issuance of Registration Letter.**

1085	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hygeia Pharmaceuticals, Plot No. 295, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Rotex Pharma (Pvt) Ltd, Plot # 206 & 207, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**Rotex pharma:** GMP certificate issued on the basis of inspection dated 12-08-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000651 of M/s Rotex Pharma Islamabad dated 13-06-2017 specifying dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18476: 01-07-2021
	Details of fee submitted	PKR 50,000/-: 26-02-2021
	The proposed proprietary name / brand name	**MEROMAX 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem trihydrate eq to meropenem……1g (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials with dark blue flip off seal
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic

	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
	Module-II (Quality Overall Summary)	
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 1g Injection of Pfizer Pakistan Ltd manufactured by ACS Dobfar Italy.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Sterile India Pvt Ltd. Plot No. 100& 118-G, Phase-IV, Sector-56, HSIIDC, Industrial Estate Kundli District Sonepat Haryana India.
API Lot No.	
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C161001	C161002	C161003
Batch Size	3521 vials	3521 vials	3521 vials
Manufacturing Date	09-2018	10-2018	11-2018
Date of Initiation	19-09-2018	09-11-2018	29-12-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

The product development and stability study data of the contract manufacturer was considered by Registration Board in its 312nd meeting and observed that the contract manufacturer has not performed complete product development studies, and the specifications adopted by the manufacturer throughout stability studies were not according to USP and further observed that the stability batches have expired. Accordingly, the Board deferred for following submissions:

- Scientific justification for having the method of sample solution preparation for the commercial batches which is entirely different from that specified in USP monograph.
- Scientific justification for not performing compatibility studies with the recommended diluent.
- Scientific justification for using an entirely different formula for calculation of assay results of commercial batches from that specified in USP monograph.
- Scientific justification for not performing test of sodium content.
- Scientific justification for not performing critical tests like constituted solution, and loss on drying during the stability studies.
- Scientific justification for performing stability studies in which the test of bacterial endotoxin and sterility is not performed at 6 months time interval.
- Scientific justification for using only 3 chromatograms of the standard solution for HPLC testing while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Evidence of purchase of atomic absorption spectrophotometer including commercial invoice and Installation Qualification (IQ) and Operational Qualification (OQ) of atomic absorption alongwith performance data for sodium content test on stability batches.
- Submission of fee for pre-registration changes in the drug product specifications.

The Board further decided that the submitted stability study data is not acceptable and directed the contract manufacturer to either perform complete product development and stability studies as per USP specifications or submit aforementioned data for commercial batches manufactured as per USP specifications.

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

1086	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jupiter Pharma, Plot # 25, S-6, National Industrial Zone Rawat Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Lyophilized vial (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Lyophilized vial (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16110: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 02-04-2021
	The proposed proprietary name / brand name	**JUTIG Injection 50mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Tigecycline……50mg
	Pharmaceutical form of applied drug	Almost yellow colored lyophilized powder
	Pharmacotherapeutic Group of (API)	Antibacterial agent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tygacil Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Tygacil Injection by Pfizer
	Name and address of API manufacturer.	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd. No. 1 Huanan Yi Road, Changshou District Chongqing China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed pharmaceutical equivalence against the product BTig 50 mg injection by Bosch Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuan Pharmaceutical Group Chongqing Bosen Pharmaceutical Co. Ltd. No. 1 Huanan Yi Road, Changshou District Chongqing China.		
API Lot No.			
Description of Pack (Container closure system)	Glass Vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	L-131	L-138	L-242
Batch Size	1,000 Packs	1,000 Packs	700 Packs
Manufacturing Date	01-2018	01-2018	08-2019
Date of Initiation	20-03-2018	12-03-2018	01-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. CQ20180031) issued by CFDA China. The certificate is valid till 09-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement.
- Provide label claim as per the innovator's product in module 1.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Justify how the drug substance specifications conforms to USP, since the acceptance criteria for various tests is different from USP monograph.
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Provide COA of relevant batch of drug substance used in the manufacturing of batches for which stability study data is submitted.
- Justify the stability studies of the drug substance as per zone IV-A conditions, since as per API manufacturer as well as USP the storage conditions is to store the drug substance from 2 to 8 degree.
- Justify the pharmaceutical equivalence studies against the comparator product instead of performing these studies against the innovator / reference product.
- Justify why complete tests as mentioned in USP are not performed during pharmaceutical equivalence studies.
- Provide detailed method of manufacturing including details of the amount of distilled water added to prepare the solution and the pH range which is maintained for that solution and exact temperature and total time used for lyophilization process.
- Justify your process validation protocols and reports which does not include any step for optimization of the solution preparation and lyophilization process.
- Provide details of the lyophilizer installed in your premises including details of the minimum and maximum capacity of the equipment.
- Provide evidence of autosampler and low actinic glassware to carry out the analysis of the drug product.
- Provide results of verification studies of the analytical method of drug product in the light of ICH guidelines.
- Batch L-131 and L-138 are manufactured using drug substance from any other source while the batch L-242 was manufactured using drug substance from the source which is mentioned in module 3. Justification is required in this regard.

• Justify how three injections of standard solution were used for the assay testing of the drug product in stability studies. • Provide Reference of previous approval of applications with stability study data of the firm (if any) instead of mentioning not applicable. • Provide Documents for the procurement of API with approval from DRAP (in case of import) for the relevant batch of drug substances which are used in the manufacturing of 3 batches of drug product whose stability data is submitted in section 3.2.P.8.3. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide batch manufacturing record of three stability batches.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1087	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories, Plot # 121 Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 03-11-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16115: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 30-04-2021
	The proposed proprietary name / brand name	**DAVICOBAL Injection 500mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1 ml ampoule Contains: Mecobalamin……500mcg
	Pharmaceutical form of applied drug	Almost red colour solution filled in amber glass ampoule.
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1ml x 10's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Mecobalamin 500mcg Injection **(PMDA** Japan Approved)
	For generic drugs (me-too status)	Mecomax Injection by Global Pharma
	Name and address of API manufacturer.	M/s. Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30^{o}C ± 2^{o}C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has performed pharmaceutical equivalence against the product Methycobal 500 mg injection by Hilton Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s. Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India
API Lot No.	MCB2010061
Description of Pack	Glass ampoule

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-431	A-443	A-456
Batch Size	37,000 Ampoules	10,000 Ampoules	10,800 ampoules
Manufacturing Date	04-2018	05-2018	06-2018
Date of Initiation	29-8-2018	02-07-2018	10-09-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate # 20031928 of M/s. Vital Laboratories (Pvt) Ltd. Plant II, Plot No. 1710, GIDC Estate, Phase III, Vapi – 396 195 Gujrat India valid upto 16-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted attested copy of invoice (invoice # HHM/2021/00256) attested by AD DRAP
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Provide label claim as per the innovator's product in module 1.
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Provide COA of relevant batch of drug substance used in the manufacturing of batches for which stability study data is submitted, since the submitted COA is of batch manufactured in 2020, while stability batches were manufactured in 2018.
- Justify your master formulation in which sodium chloride, propylene glycol, benzyl alcohol, sodium acetate and water for injection is used as excipient, since the innovator product only use D-mannitol and pH regulator.
- Justify the use of preservative in a single dose ampoule preparation.

- Justify the use of around 45% overage of active ingredient in your master formulation while USP recommends much lower overage for vitamin B12.
- Justify why complete tests as mentioned in general monographs for such preparations are not performed during pharmaceutical; equivalence studies.
- Justify how pharmaceutical equivalence studies were conducted with results of assay 127.80% and 128.30% for test and comparator product in the light of USP general chapters and allowable limit of overages for vitamin B12.
- Justify why the test for particulate matter, uniformity of dosage unit and antimicrobial preservative content / effectiveness is not included in the drug product specifications, since these tests are recommended in general monograph of USP.
- Justify the pH value of 5 – 7, since the pH of the innovator's product is 5.3 – 7.3. Revise your specifications along with submission of requisite fee.
- Justify the analytical method for assay and identification test based on UV method, since the drug substance manufacturer's method as well as the innovator product analytical method is based on HPLC testing.
- Justify the validation studies based on UV method, since the innovator's product methodis based on HPLC testing.
- Justify how the three batches i.e. I-150, I-163 and I-173 were released in 2019 having assay values of 100, 100.1and 100.2% respectively while 145% overage of the active ingredient was added.
- Provide COA of reference standard actually used in the analysis of drug product.
- Provide batch number in terms of number of ampoules for batch A-431.
- Provide exact lot number of COA of drug substance used in manufacturing of each batch of drug product.
- Justify the results of assay as all the batches just showed minor decrease in assay results less than which is usually observed in vitamin preparations. Scientific justification / clarification is required in this regard.
- Justify why photostability studies are not performed for the drug product.
- Provide Reference of previous approval of applications with stability study data of the firm (if any) instead of mentioning not applicable.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide batch manufacturing record of three stability batches.
- Specify the details how the manufacturing and analysis of the product was carried out without exposure to light. Further also provide evidence of light resistant vessels to carry out analysis as recommended in JP monograph.

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

1088	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories, Plot # 121 Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the

		inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16114: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 30-04-2021
	The proposed proprietary name / brand name	**NALPHIN Injection 10mg/mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Nalbuphine HCl……10mg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml **(USFDA** Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Kinz injection of Sami Pharma
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and validation studies of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri		
API Lot No.	~~1909000314~~		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-429	A-552	A-608
Batch Size	15000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	04-2018	01-2019	04-2019
Date of Initiation	28-05-2018	06-02-2019	24-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-01-2020 specifying import of 0.05Kg nalbuphine hydrochloride. The invoice is **not** attested by AD (I&E) DRAP Field office. Firm has also submitted copy of Form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.

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

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit contract manufacturing agreement between contract giver and contract acceptor.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Submit data of batch analysis of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture"* since the submitted COA is for the batch manufactured in December 2020 while the drug product batches were manufactured in 2018 and 2019.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify your master formulation without any solvent / diluent, further justify how you are using sodium chloride as solvent.
- Justify your master formulation which is significantly different from the innovator product in terms of quantitative composition where you have used sodium citrate, sodium chloride and citric acid anhydrous in 29.71%, 6.34% and 36.03% respectively, since the innovator product specifies sodium citrate, sodium chloride and citric acid anhydrous in 0.94%, 0.2% and 1.26% respectively.
- Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify how you are not performing terminal sterilization for your product.
- Specify the container closure system whether available in amber color glass ampoule or otherwise.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain complete tests as recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify the pH of your product between 3 to 4.5 since the pH of the innovator product is 3.5 to 3.7. Revise your specifications along with submission of requisite fee.
- Justify your analytical method for assay testing of the drug product which is based on UV analysis, since the analytical method of drug substance manufacturer as well as innovator / reference product is based on HPLC method.
- Justify your validation studies of the drug product in the light of ICH guidelines, since your analysis and reporting of the results is not exactly in line with the ICH recommendations.
- Justify why the stability study data of three different batches is submitted from those for which batch analysis is provided in section 3.2.P.5.4.

- You have submitted that the drug substance manufacturer is Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri, but the drug substance used in the manufacturing of 3 batches of drug product is from any other source. Justification is required in this regard.
- Justify significant difference in the batch size of your products ranging from 15,000 to 50,000 ampoules. Justify your response in the light of the minimum and maximum capacity of your manufacturing equipments.
- Justify the pH of batch A-608 where the pH value exceed 3.70 to 3.78 during stability studies, since the maximum pH limit defined by innovator product is 3.70.
- Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. Submit complete data with proper separators and in a sequence along with raw data sheets.
- Submit reference of previous approval of applications with stability study data of the firm instead of mentioning not applicable.
- Submit valid GMP certificate of the drug substance manufacturer.
- Submit documents for the procurement of API with approval from DRAP for the relevant batch of API which is used in the manufacturing of stability batches.
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.
- Submit copy of batch manufacturing record of 3 stability batches.

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

1089	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Alliance Pharmaceuticals (Pvt) Ltd. 112-A Industrial Estate Hayatabad Peshawar.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 01-04-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Liquid ampoule (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Ampoule (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16111: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 07-04-2021
	The proposed proprietary name / brand name	**ALLOPHINE Injection 10mg/mL**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Nalbuphine HCl……10mg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	Morphinan derivatives
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nalbuphine Injection 10mg/ml **(USFDA** Approved)
	For generic drugs (me-too status)	Nalbin Injection by Global Pharma
	Name and address of API manufacturer.	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Kinz injection of Sami Pharma

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

STABILITY STUDY DATA

Manufacturer of API	Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri		
API Lot No.			
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-429	A-552	A-608
Batch Size	15000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	04-2018	01-2019	04-2019
Date of Initiation	28-05-2018	06-02-2019	24-05-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 10-01-2020 specifying import of 0.05Kg nalbuphine hydrochloride. The invoice is **not** attested by AD (I&E) DRAP Field office. Firm has also submitted copy of Form 3 and form 7.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."

- Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".*
- Submit data of batch analysis of drug substance in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that *"Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture"* since the submitted COA is for the batch manufactured in December 2020 while the drug product batches were manufactured in 2018 and 2019.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify your master formulation without any solvent / diluent, further justify how you are using sodium chloride as solvent.
- Justify your master formulation which is significantly different from the innovator product in terms of quantitative composition where you have used sodium citrate, sodium chloride and citric acid anhydrous in 29.71%, 6.34% and 36.03% respectively, since the innovator product specifies sodium citrate, sodium chloride and citric acid anhydrous in 0.94%, 0.2% and 1.26% respectively.
- Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify how you are not performing terminal sterilization for your product.
- Specify the container closure system whether available in amber color glass ampoule or otherwise.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain complete tests as recommended by innovator product as well as the tests recommended in general monographs of official pharmacopoeia.
- Justify the pH of your product between 3 to 4.5 since the pH of the innovator product is 3.5 to 3.7. Revise your specifications along with submission of requisite fee.
- Justify your analytical method for assay testing of the drug product which is based on UV analysis, since the analytical method of drug substance manufacturer as well as innovator / reference product is based on HPLC method.
- Justify your validation studies of the drug product in the light of ICH guidelines, since your analysis and reporting of the results is not exactly in line with the ICH recommendations.
- Justify why the stability study data of three different batches is submitted from those for which batch analysis is provided in section 3.2.P.5.4.
- You have submitted that the drug substance manufacturer is Mallinckrodt Pharmaceuticals SpecGx LLC 3600 North Second Street St. Louis, Missouri, but the drug substance used in the manufacturing of 3 batches of drug product is from any other source. Justification is required in this regard.
- Justify significant difference in the batch size of your products ranging from 15,000 to 50,000 ampoules. Justify your response in the light of the minimum and maximum capacity of your manufacturing equipments.
- Justify the pH of batch A-608 where the pH value exceed 3.70 to 3.78 during stability studies, since the maximum pH limit defined by innovator product is 3.70.
- Provide raw data sheets to justify the calculation of results for assay testing at each time point during the stability testing of each batch. Submit complete data with proper separators and in a sequence along with raw data sheets.
- Submit reference of previous approval of applications with stability study data of the firm instead of mentioning not applicable.
- Submit valid GMP certificate of the drug substance manufacturer.
- Submit documents for the procurement of API with approval from DRAP for the relevant batch of API which is used in the manufacturing of stability batches.
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.
- Submit copy of batch manufacturing record of 3 stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1090	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Farm Aid Group Pharmaceuticals, 3/2 Phase-I & II Hattar Industrial Estate Hattar, Haripur.**
	Name, address of Manufacturing site	M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 19-10-2020.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License of M/s Cure Laboratories (Pvt) Ltd dated 05-03-2019 specifying Dry Powder vial (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16363: 14-06-2021
	Details of fee submitted	PKR 50,000/-: 23-11-2020
	The proposed proprietary name / brand name	**SOCEF 1g Injection IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……1g
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 1g Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	Q012002060		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20025	20026	20027
Batch Size	4166 vials	4166 vials	4166 vials
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SX20180229) issued by CFDA China dated 06-06-2018. The GMP certificate is valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Provide valid GMP certificate of the drug product manufacturer.
- Justify the drug substance specifications submitted in section 3.2.S.4.1 which states that the material is non-sterile and the assay limit is 98 – 102% which is contrary to that specified in USP monograph for ceftriaxone for injection. Furthermore, clarify whether you have used sterile ready to fill drug substance or non-sterile ceftriaxone sodium.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Justify how the drug substance batch No. Q012002060 was released on 18-05-2020 without performing sterility test since this test is mentioned in the drug substance specifications as well as COA of drug substance manufacturer. Justify how 200kg material was released for production without performing sterility test.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify the label claim submitted in section 3.2.P.1 which specifies that each vial contains 1g ceftriaxone sodium.
- Justify how 1200mg ceftriaxone sodium sterile powder per vial will be equivalent to 1g of ceftriaxone base.
- Specify the type of diluent along with its exact volume which is to be used for the reconstitution of the applied product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product as per USP specifications. Justify how only pH and assay test can demonstrate pharmaceutical equivalence.
- Provide details including the batch number, expiry date and manufacturer of the comparator product against which pharmaceutical equivalence is conducted.
- Justify why compatibility study of the drug product along with recommended diluent is not performed as per the requirement of section 3.2.P.2.6. Further justify how you have completed product development without performing complete studies.
- Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc. Further justify why complete process validation is not performed since commercial batches of the drug product have been manufactured by the manufacturer.

- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain important tests as recommended by USP including test for constituted solution, particulate matter in injection, crystallinity and complete assay test.
- Provide detailed testing method for the drug product as per the USP specifications since the submitted method is not complete. Also submit fee for revision of specifications in the light of USP monograph.
- Clarify the sample solution preparation method in your analysis which states "constitute ceftriaxone for injection in a volume of water corresponding to the volume of solvent specified in the labelling". Specify what is the exact volume in which reconstitution is to be carried out instead of mentioning generalized statements.
- Justify how three commercial batches were released for commercial use without performing complete tests as specified in USP monograph.
- Provide COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
- Provide details of the primary and secondary packaging material of the drug product including details of type, colour and specifications of the glass vial, rubber stopper and seal etc. in section 3.2.P.7.
- The batches are released after 16-06-2020, while the stability studies were initiated on 02-06-2020. Justify how the batch could be initiated for stability studies before the batch release.
- Justify why the test for bacterial endotoxin, sterility, water contents, constituted solution etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life.
- Justify the raw data sheets in which sample preparation method is incomplete.
- Justify how only single value of peak area of standard and sample is used to calculate the assay of drug product during stability studies.
- Submit date of initiation of stability studies for all the three batches.
- Justify the testing at 3rd month time point on 25-08-2020 while the batches were released after 16-06-2020. Provide complete justifications of the stability schedule with respect to testing time points to justify that 6 months stability studies have been conducted and the time period between 0 to 3rd month and 3rd to 6th month is justifiable in the light of ICH / WHO guidelines.
- Provide stability data sheets for all the batches as per the template provided in the CTD guidance document since your template does not contain various information like stability initiation date, API lot number, date of testing at 0 month, 3rd month and 6th month time point.
- Provide complete record of the stability testing of each batch with proper separators in a sequence instead of separately providing the data without any sequence.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
- Justify the manufacturing of batches having 4166 batch size in which 5Kg of drug substance was used, keeping in view the fact that the drug substance also contains 9.1% water which is evident from the COA of the relevant batch of drug substance.
- Justify the supply of 5ml WFI along with ceftriaxone sodium 1g IV injection since the innovator product recommends different quantity of diluent.

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

1091	**Name, address of Applicant / Mar keting Authorization Holder**	**M/s Farm Aid Group Pharmaceuticals, 3/2 Phase-I & II Hattar Industrial Estate Hattar, Haripur.**
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt) Ltd. Plot # 11-12, Street # NS-2, RCCI Industrial Estate, Rawat Islamabad.
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 19-10-2020.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License of M/s Cure Laboratories (Pvt) Ltd dated 05-03-2019 specifying Dry Powder vial (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16362: 14-06-2021
	Details of fee submitted	PKR 50,000/-: 23-11-2020
	The proposed proprietary name / brand name	**SOCEF 500mg Injection IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone (as sodium)……500mg
	Pharmaceutical form of applied drug	Sterile white to off white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ceftriaxone sodium Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Aczon injection by Vision Pharma
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Rocephin 500mg Injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co. Ltd. First Medical Zone, Economic and Technological Development Zone, Datong Shanxi. China		
API Lot No.	Q012002060		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20031	20032	20033
Batch Size	2500 vials	2500 vials	2500 vials
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	16-06-2020	16-06-2020	~~18-06-2020~~
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SX20180229) issued by CFDA China dated 06-06-2018. The GMP certificate is valid till 05-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

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

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Provide valid GMP certificate of the drug product manufacturer.
- Justify the drug substance specifications submitted in section 3.2.S.4.1 which states that the material is non-sterile and the assay limit is 98 – 102% which is contrary to that specified in USP monograph for ceftriaxone for injection. Furthermore, clarify whether you have used sterile ready to fill drug substance or non-sterile ceftriaxone sodium.
- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Justify how the drug substance batch No. Q012002060 was released on 18-05-2020 without performing sterility test since this test is mentioned in the drug substance specifications as well as COA of drug substance manufacturer. Justify how 200kg material was released for production without performing sterility test.
- Provide COA of reference standard which is actually used in the analysis of drug substance in section 3.2.S.5.
- Justify the label claim submitted in section 3.2.P.1 which specifies that each vial contains 500mg ceftriaxone sodium.
- Justify how 600mg ceftriaxone sodium sterile powder per vial will be equivalent to 500mg of ceftriaxone base.
- Specify the type of diluent along with its exact volume which is to be used for the reconstitution of the applied product.
- Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product as per USP specifications. Justify how only pH and assay test can demonstrate pharmaceutical equivalence.
- Provide details including the batch number, expiry date and manufacturer of the comparator product against which pharmaceutical equivalence is conducted.
- Justify why compatibility study of the drug product along with recommended diluent is not performed as per the requirement of section 3.2.P.2.6. Further justify how you have completed product development without performing complete studies.
- Justify your process validation protocols without any process for optimization of sterilization process and sealing of vials etc. Further justify why complete process validation is not performed since commercial batches of the drug product have been manufactured by the manufacturer.
- Justify why the specifications of the drug product (section 3.2.P.5.1) does not contain important tests as recommended by USP including test for constituted solution, particulate matter in injection, crystallinity and complete assay test.
- Provide detailed testing method for the drug product as per the USP specifications since the submitted method is not complete. Also submit fee for revision of specifications in the light of USP monograph.
- Clarify the sample solution preparation method in your analysis which states "constitute ceftriaxone for injection in a volume of water corresponding to the volume of solvent specified in the labelling". Specify what is the exact volume in which reconstitution is to be carried out instead of mentioning generalized statements.
- Justify how three commercial batches were released for commercial use without performing complete tests as specified in USP monograph.

- Provide COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
- Provide details of the primary and secondary packaging material of the drug product including details of type, colour and specifications of the glass vial, rubber stopper and seal etc. in section 3.2.P.7.
- The batches are released after 16-06-2020, while the stability studies were initiated on 02-06-2020. Justify how the batch could be initiated for stability studies before the batch release.
- Justify why the test for bacterial endotoxin, sterility, water contents, constituted solution etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life.
- Justify the raw data sheets in which sample preparation method is incomplete.
- Justify how only single value of peak area of standard and sample is used to calculate the assay of drug product during stability studies.
- Submit date of initiation of stability studies for all the three batches.
- Justify the testing at 3rd month time point on 25-08-2020 while the batches were released after 16-06-2020. Provide complete justifications of the stability schedule with respect to testing time points to justify that 6 months stability studies have been conducted and the time period between 0 to 3rd month and 3rd to 6th month is justifiable in the light of ICH / WHO guidelines.
- Provide stability data sheets for all the batches as per the template provided in the CTD guidance document since your template does not contain various information like stability initiation date, API lot number, date of testing at 0 month, 3rd month and 6th month time point.
- The results of accelerated stability study data of batch 20033 shows significant change (i.e. the assay value increase from 97.54% at initial time point to 104.93% at 6th month time point), justify how the evaluation for the significant change is not made in light of ICH guidelines.
- Provide complete record of the stability testing of each batch with proper separators in a sequence instead of separately providing the data without any sequence.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
- Submit Batch Manufacturing Record of three batches for which stability study data is submitted.

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

1092	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 10-11-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the

		inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16116: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 09-04-2021
	The proposed proprietary name / brand name	**VARICEF 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime as trihydrate……400mg
	Pharmaceutical form of applied drug	Orange / ivory colored hard gelatin capsule shells size 0 filled with almost off white to light yellow colored granular powder
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.

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

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.		
API Lot No.	18CF101233 17CF101233 17CF101235		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	271	267	261
Batch Size	60,000 capsule	25,000 capsule	25,000 capsule
Manufacturing Date	07-2018	06-2018	05-2018
Date of Initiation	31-07-2018	31-07-2018	04-07-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Karachi dated 23-06-2020. The GMP certificate was granted based on inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA

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

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.
- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 and in-house specifications in module 2 section 2.3.P.5.1 while the drug product monograph is available in JP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.
- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2018.
- Justify the use of overage in the formulation to compensate the potency of the product during process loss.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product.
- Justify how you have performed comparative dissolution profile by taking only three time points, also justify how 30, 45 and 60 minutes time point was selected during the CDP studies. Also clarify why the initial time point was taken at 30 minutes for an immediate release dosage form.
- Provide detailed analytical method along with dissolution parameters used during the comparative dissolution profile study. Also provide detailed results of comparative dissolution profile studies.
- Justify how mixing time has been finalized during the process validation studies.
- Justify why the test for water content is not performed for the drug product.
- Justify how you have performed dissolution test since your submitted method of analysis for this test does not provide details for sample solution preparation or standard preparation. Furthermore no formula for calculation of the results is provided.
- Justify why the analytical method for dissolution test for cefixime capsule is based on UV method instead of using HPLC method which have been used by the innovator product as well as also specified in JP monograph.
- Justify why the assay test is performed using UV method while the method of analysis of drug substance manufacturer and the innovator product is based on HPLC method. Furthermore the JP monograph also specifies HPLC test for assay method for cefixime capsule.

• Justify the analytical method validation studies which have been performed at totally different concentrations than that specified in the assay method. The assay method specify that the concentration of sample and standard solution is 0.02mg/ml while the validation studies have been performed at very high concentrations. • The process validation studies have been conducted on three batches having 10,000 capsule batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from 25,000 to 60,000 Capsule. Justification is required in this regard. • Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6, since you have submitted USP certificate for Lot No. R03930 which was valid till 31-10-2019. Further submit evidence of purchase of the particular lot number of USP reference standard. • Specify the date of initiation of stability studies for all the stability batches. • Justify why weight variation test is not performed during the stability studies. • Justify how the results of assay and dissolution test at initial time point is different at both real time and accelerated conditions. • Justify why you have mentioned not applicable against "Reference of previous approval of applications with stability study data of the firm (if any)" since various inspections of bio labs have been conducted to verify the stability study data. • Submit copy of commercial invoice for evidence of purchase of each batch of drug substance that have been used in the analysis of each batch of drug product. • Batch 261 was manufactured on 05-2018, the initial testing of real time studies was conducted on 04-07-2018 while the accelerated stability testing of initial time point was conducted on 15-05-2018. Justify how this stability design is considered appropriate where different testing has been conducted for initial studies, moreover the testing time for both accelerated and real time stability studies have difference of approximately 2 months. • Submit batch manufacturing record (BMR) of the three batches for which stability study data has been submitted, since the submitted BMRs are of different batches.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1093	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 10-11-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17791: 25-06-2021
	Details of fee submitted	PKR 50,000/-: 09-04-2021
	The proposed proprietary name / brand name	**VARICEF 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……100mg
	Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flavour powder for reconstitution
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	~~USP~~
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefspan dry suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.		
API Lot No.	18CF10035		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	D-006	D-018	D-022
Batch Size	80 Kg	10125 packs	5000 bottles
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	31-01-2019	31-01-2019	31-01-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Karachi dated 23-06-2020. The GMP certificate was granted based on inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.

- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.
- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 0.685gm of drug substance is equivalent to 100mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 7500 and as high as 60,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for batch D-220, D-221 and D-222 in section 3.2.P.5.4 while provided stability study data for batch D-006, D-018 and D-022 in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.

- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing
- Justify why BMR of different batches is submitted than that for which stability studies were conducted.

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

1094	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals Pvt Ltd. Plot No. 5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 10-11-2020.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies oral dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17790: 25-06-2021
	Details of fee submitted	PKR 50,000/-: 09-04-2021
	The proposed proprietary name / brand name	**VARICEF 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	Almost pink colored powder having strawberry flavour powder for reconstitution

	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	~~USP~~
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefspan dry suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
API Lot No.	18CF10035

Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	553	589	597
Batch Size	7500 packs	10000 packs	10000 packs
Manufacturing Date	05-2018	08-2018	09-2018
Date of Initiation	10-05-2018	31-08-2018	28-09-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Karachi dated 23-06-2020. The GMP certificate was granted based on inspection dated 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Submit valid contract manufacturing agreement between the contract giver and contract acceptor.
- Submit module 1 as per the CTD guidance document approved by Registration Board by providing all the information and documents in relevant sections / sub-sections instead of referring to annexures.
- Submit label claim in module 1 as per the reference product along with submission of requisite fee.
- You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in USP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both BP and USP specifications for the drug substance, provide scientific justification in this regard.
- The drug substance manufacturer has claimed USP specifications for the assay method, while the submitted method is different from USP in terms of column specifications including column length and pore size. Justification is required in this regard.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine

testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."

- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of 2020 while the drug product batches were manufactured in 2019.
- Justify how your unit formula containing 1.368gm of drug substance is equivalent to 200mg cefixime base per 5ml after reconstitution. Further specify which is the unit which has been taken as reference for your formulation.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product Suprax suspension.
- Innovator product has not used sodium citrate which is used in your formulation as preservative along with sodium benzoate. Justify the use of two different preservatives without determining the preservative effectiveness.
- The acceptance criteria for pH is 2.5 to 4.5 while your compatibility results specifies that after reconstitution with the recommended diluent / solvent, the pH is 5.08 which lies outside the acceptance criteria. Justify how you have passed this formulation and performed stability studies on the same formulation.
- The process validation studies have been conducted on three batches having 5000 bottles batch size. While the batch size of the commercial batches for which stability study data is submitted, ranges from as low as 3000 and as high as 10,000 bottles. Justification is required in this regard.
- Submit detailed method of analysis of the drug product in section 3.2.P.5.2 instead of submitting print of USP monograph.
- Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.
- Justify the analytical method verification studies without performing test or specificity and precision. Further also specify the exact concentration of solutions of 50%, 100% and 150% solutions used in the analysis of accuracy and recovery test.
- Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.
- You have provided batch release certificate for different batches in section 3.2.P.5.4 while the stability study data of different batches is submitted in section 3.2.P.8.3. Clarification is required in this regard.
- Provide batch size of Batch D-006 in terms of number of bottles instead of providing batch size in terms of Kg.
- You have submitted that API lot used in manufacturing of stability batches is 18CF10035 while submitted COA of totally different batches in section 3.2.S.4.4. Justify why data was not submitted in line with the guidance document issued by Registration Board.
- Justify why only 3 chromatographs of the standard solution was run while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Provide raw data sheets showing calculation of the results during the stability studies for all batches.
- Justify why the stability study data is section 3.2.P.8.3 is not submitted as per the guidance document issued by Registration Board.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing

• Justify why BMR of different batches is submitted than that for which stability studies were conducted. • Justify the criteria for selecting batch number and batch size of your product, since different format of batch numbers have been used for different batches, while significant difference in batch size also exist among various production scale batches.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1095	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hygeia Pharmaceuticals, Plot No. 295, Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Rotex Pharma (Pvt) Ltd, Plot # 206 & 207, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**Rotex pharma:** GMP certificate issued on the basis of inspection dated 12-08-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section / amendment under DML No 000651 of M/s Rotex Pharma Islamabad dated 13-06-2017 specifying dry powder injection (carbapenem) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13084: 05-05-2021
	Details of fee submitted	PKR 50,000/-: 26-02-2021
	The proposed proprietary name / brand name	**MEROMAX 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem trihydrate eq to meropenem……500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	White to off white powder filled in clear glass vials
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection **(USFDA** Approved)
	For generic drugs (me-too status)	Merrem Injection of Global Pharmaceuticals
	Name and address of API manufacturer.	
	Module-II (Quality Overall Summary)	
	Module-III Drug Substance:	
	Stability Studies of Drug Substance	

	(Conditions & duration of Stability studies)	
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

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

Evaluation by PEC:

The product development and stability study data of the contract manufacturer was considered by Registration Board in its 312nd meeting and observed that the contract manufacturer has not performed complete product development studies, the specifications adopted by the manufacturer throughout stability studies were not according to USP and that the stability batches have also expired. Accordingly, the Board deferred for following submissions:

- Scientific justification for having the method of sample solution preparation for the commercial batches which is entirely different from that specified in USP monograph.
- Scientific justification for not performing compatibility studies with the recommended diluent.
- Scientific justification for using an entirely different formula for calculation of assay resultsof commercial batches from that specified in USP monograph.
- Scientific justification for not performing test of sodium content.
- Scientific justification for not performing criticial tests like constituted solution, and loss on drying during the stability studies.
- Scientific justification for performing stability studies in which the test of bacterial endotoxin and sterility is not performed at 6 months time interval.
- Scientific justification for using only 3 chromatograms of the standard solution for HPLC testing while USP General chapter <621> recommends that five replicates of standard solution should be used for system suitability studies.
- Evidence of purchase of atomic absorption spectrophotometer including commercial invoice and Installation Qualification (IQ) and Operational Qualification (OQ) of atomic absorption along with performance data for sodium content test on stability batches.
- Submission of fee for pre-registration changes in the drug product specifications.

The Board further decided that the submitted stability study data is not acceptable and directed the contract manufacturer to either perform complete product development and stability studies as per USP specifications or submit aforementioned data for commercial batches manufactured as per USP specifications.

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

1096	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Stanley Pharmaceuticals (Pvt) Ltd. 84-B Industrial Estate Hayatabad Peshawar.**
	Name, address of Manufacturing site.	M/s Stanley Pharmaceuticals (Pvt) Ltd. 84-B Industrial Estate Hayatabad Peshawar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26756 : 11-12-2019
	Details of fee submitted	PKR 20,000/-: 11-12-2019
	The proposed proprietary name / brand name	**Pedrol CF Day Caplet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated caplet contains: Paracetamol …….500mg Phenylephrine HCl……..5mg
	Pharmaceutical form of applied drug	
	Pharmacotherapeutic Group of (API)	
	Reference to Finished product specifications	
	Proposed Pack size	
	Proposed unit price	
	The status in reference regulatory authorities	Medreich Cold and Flu Relief PE Day tablet **(TGA** Approved)
	For generic drugs (me-too status)	Panadol CF Day Caplet by GSK (Reg # 094797)

	Name and address of API manufacturer.	
	Module-II (Quality Overall Summary)	
	Module-III Drug Substance:	
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T004	T005	T006
Batch Size	2000 tablet	2000 tablet	2000 tablet
Manufacturing Date	02-2019	02-2019	02-2019
Date of Initiation	28-02-2019	28-02-2019	28-02-2019
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	
3.	Protocols followed for conduction of stability study and details of tests.	
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	

5.	Documents confirming import of API etc.	
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	
7.	Commitment to continue real time stability study till assigned shelf life of the product.	
8.	Commitment to follow Drug Specification Rules, 1978.	

REMARKS OF EVALUATOR

- Drug substance related information including name and address of API manufacturer, and approval of manufacturing facility of API manufacturer by regulatory body of the concerned country as per the requirements of sub section 1.6.5 needs to be submitted.
- Quality overall summary (QOS) in module 2 needs to be submitted as per WHO QOS - PD template.
- Complete information related to drug substance as per requirement of sub section 3.2.S needs to be submitted in the light of guidance document approved by Registration Board in its 293rd meeting.
- Complete information related to drug product as per requirement of sub section 3.2.P needs to be submitted in the light of guidance document approved by Registration Board in its 293rd meeting.
- Submit stability study data of 3 batches of drug product along with associated data / documents (as per 6 points checklist) as per the guidance document approved by Registration Board in its 293rd meeting.

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

Item No. XVII: Agenda of Evaluator II:

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

a. New cases

1097.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	T penol XR 200mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Tapentadol HCl …..…200mg
	Diary No. Date of R& I & fee	Dy.No 13601 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Analgesics, Opiods
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	

	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1098.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	T penol 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol HCl …..…100mg
	Diary No. Date of R& I & fee	Dy.No 13599 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Analgesics, Opiods
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1099.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	T penol 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol HCl …..…50mg
	Diary No. Date of R& I & fee	Dy.No 13600 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Analgesics, Opiods
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1100.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	T penol 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Tapentadol HCl …..…75mg
	Diary No. Date of R& I & fee	Dy.No 13605 dated 07-03-2019, Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Analgesics, Opiods
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1101.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Hepvir B Tablet 0.5mg
	Composition	Each Film Coated Tablet Contains: Entecavir…….0.5mg
	Diary No. Date of R& I & fee	Dy.No 13598 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antivirals for systemic use
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Cavirent Tablet 0.5mg by M/s CKD Pharmaceuticals Reg#092969)
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring the hydrate form of Entecavir, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim along with master formulation and fee of Rs. 30,000/- vide deposit slip# 32870446717: "Each Film Coated Tablet Contains: Entecavir monohydrate eq. to Entecavir ……. 0.5mg"	
	Decision: Approved as per following label claim: **"Each Film Coated Tablet Contains:** **Entecavir monohydrate eq. to Entecavir ……. 0.5mg"**	
1102.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Hepvir B Tablet 1mg
	Composition	Each Film Coated Tablet Contains: Entecavir…….1mg
	Diary No. Date of R& I & fee	Dy.No 13604 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antivirals for systemic use
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Cavirent Tablet 1mg by M/s CKD Pharmaceuticals (Reg#092968)
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring the hydrate form of Entecavir, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	

	• Firm has submitted revised label claim along with master formulation and fee of Rs. 30,000/- vide deposit slip# 235793008: "Each Film Coated Tablet Contains: Entecavir monohydrate eq. to Entecavir ……. 1mg"	
	Decision: Approved as per following label claim: **"Each Film Coated Tablet Contains:** **Entecavir monohydrate eq. to Entecavir ……. 1mg"**	
1103.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Barifer Solution for Injection 1000mg/10ml
	Composition	Each 10ml Ampoule Contains: Iron as Iron (III) Isomaltoside 1000……..1000mg
	Diary No. Date of R& I & fee	Dy.No 13609 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator [II]: Evidence of applied formulation/drug in the applied fill volume of 10ml, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or submit stability study data as per the guidelines approved in 293rd meeting of Registration Board along with Form 5D and differential fee as per notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Deferred for evidence of applied formulation/drug in the applied fill volume of 10ml, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or submit stability study data as per the guidelines approved in 293rd meeting of Registration Board along with Form 5D and differential fee as per notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
1104.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Barifer Solution for Injection 500mg/5ml
	Composition	Each 5ml Ampoule Contains: Iron as Iron (III) Isomaltoside 1000……..500mg
	Diary No. Date of R& I & fee	Dy.No 13606 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator [II]: Evidence of applied formulation/drug in the applied fill volume of 5ml, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or submit stability study data as per the guidelines approved in 293rd meeting of Registration Board along with Form 5D and differential fee as per notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	

	Decision: Deferred for evidence of applied formulation/drug in the applied fill volume of 5ml, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or submit stability study data as per the guidelines approved in 293rd meeting of Registration Board along with Form 5D and differential fee as per notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
1105.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Barifer Solution for Injection 200mg/2ml
	Composition	Each 2ml Ampoule Contains: Iron as Iron (III) Isomaltoside 1000……..200mg
	Diary No. Date of R& I & fee	Dy.No 13609 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II: Evidence of applied formulation/drug in the applied fill volume of 2ml, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or submit stability study data as per the guidelines approved in 293rd meeting of Registration Board along with Form 5D and differential fee as per notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Deferred for evidence of applied formulation/drug in the applied fill volume of 2ml, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or submit stability study data as per the guidelines approved in 293rd meeting of Registration Board along with Form 5D and differential fee as per notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
1106.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Barifer Solution for Injection 100mg/1ml
	Composition	Each 1ml Ampoule Contains: Iron as Iron (III) Isomaltoside 1000……..100mg
	Diary No. Date of R& I & fee	Dy.No 13610 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Wisofer Injection of Wnsfield (Reg.# 078521)
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • **The firm shall inform area FIDfor sampling of first commercial scale batch for testing by CDL Karachi in comparison to innovator drug product i.e., Monofer injection and after satisfactory report by CDL, product will be marketed.**	

1107.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Amdap 10/1.5mg Tablet
	Composition	Each Film Coated, bilayer, modified release tablet contains: Amlodipine as Besylate…….10mg Indapamide……..1.5mg
	Diary No. Date of R& I & fee	Dy.No 13602 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive diuretic +Calcium antagonist
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	Natrilam tablets 10mg of M/s Serveir Research & Pharmaceuticals Pakistan (Reg.# 078521)
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1108.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	Amdap 5/1.5mg Tablet
	Composition	Each Film Coated, bilayer, modified release tablet contains: Amlodipine as Besylate…….5mg Indapamide……..1.5mg
	Diary No. Date of R& I & fee	Dy.No 13602 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive diuretic +Calcium antagonist
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	Natrilam tablets 5mg of M/s Serveir Research & Pharmaceuticals Pakistan (Reg.# 090507)
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1109.	**Name and address of manufacturer / Applicant**	**M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi**
	Brand Name + Dosage Form + Strength	V-Day Syrup
	Composition	Each 10 ml Contains: Glutamic Acid...3mg L-Lysine...10mg L-Ornithine...5mg Methionine...5mg L-Aspartate...5mg Calcium...15mg Chromium...5Mcg Cobalt...25Mcg

		Copper...1mg Iodine...50Mcg Iron...10mg Maganese...2mg Magnesium...30mg Molybdenum...5Mcg Potassium...2mg Selenium...3Mcg Zinc...5mg Vitamin A...0.9mg Vitamin B1...1.5mg Vitamin B2...1.2mg Vitamin B6...1mg Vitamin B12...3Mcg Vitamin C...50mg Vitamin D...10Mcg Vitamin E...3mg Nicotinamide...10mg Panthenol...5mg Folic Acid...0.1mg
	Diary No. Date of R& I & fee	Dy.No 13607 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Multi vitamin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	
	GMP status	GMP certificate issued based on inspection conducted on 06-12-2021
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
1110.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Urisol 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate …….. 5mg
	Diary No. Date of R& I & fee	Dy.No 16997 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Natrilam tablets 5mg of M/s Serveir Research & Pharmaceuticals Pakistan (Reg.# 090507)

	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1111	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Urisol 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate …….. 10mg
	Diary No. Date of R& I & fee	Dy.No 16998 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Solfine Tablet 10 mg of M/s Regal Pharmaceuticals (Reg. No.081959)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1112	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Genac 50mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Diclofenac Sodium……..50mg
	Diary No. Date of R& I & fee	Dy.No 16998 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antirheumatic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	Voltaren approved by USFDA
	Me-too status (with strength and dosage form)	Dicmaf 50mg Tablet of M/s Mafins, Karachi (Reg.# 079884)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1113	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Genac 100mg SR Tablet
	Composition	Each Extended Release Tablet Contains: Diclofenac Sodium……100mg
	Diary No. Date of R& I & fee	Dy.No 16996 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antirheumatics
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	As per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Medifenac SR 100mg Tablet of M/s M/s. Mediate Pharmaceuticals, Karachi (Reg.# 048703)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II:	
	Decision: Approved.	
1114.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Gabfil 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy.No 17000 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-epileptics
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II:	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1115.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Gabfil 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R& I & fee	Dy.No 16999 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-epileptics
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 50mg Capsule by M/s Getz Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II:	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1116.	**Name and address of manufacturer / Applicant**	**M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Brand Name + Dosage Form + Strength	Flozamin 5/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin……5mg

		Metformin HCl…….…1000mg
	Diary No. Date of R& I & fee	Dy.No 13796 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Diajard-M Tablet by Highnoon
	GMP status	Panel inspection for renewal of DML of M/s. Biogen Pharma, Rawat conducted on 25-11-2019 & 12-12-2019 concluded that the panel unanimously recommended the renewal of DML
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1117.	**Name and address of manufacturer / Applicant**	**M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Brand Name + Dosage Form + Strength	Flozamin 12.5/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin……12.5mg Metformin HCl…….…850mg
	Diary No. Date of R& I & fee	Dy.No 13781 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Diajard-M Tablet by Highnoon
	GMP status	Panel inspection for renewal of DML of M/s. Biogen Pharma, Rawat conducted on 25-11-2019 & 12-12-2019 concluded that the panel unanimously recommended the renewal of DML
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1118.	**Name and address of manufacturer / Applicant**	**M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Brand Name + Dosage Form + Strength	Flozamin 5/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin……5mg Metformin HCl…….…850mg
	Diary No. Date of R& I & fee	Dy.No 13780 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Diajard-M Tablet by Highnoon

	GMP status	Panel inspection for renewal of DML of M/s. Biogen Pharma, Rawat conducted on 25-11-2019 & 12-12-2019 concluded that the panel unanimously recommended the renewal of DML
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1119.	**Name and address of manufacturer / Applicant**	**M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Brand Name + Dosage Form + Strength	Flozamin 12.5/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin……12.5mg Metformin HCl…..…1000mg
	Diary No. Date of R& I & fee	Dy.No 13776 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Diajard-M Tablet by Highnoon
	GMP status	Panel inspection for renewal of DML of M/s. Biogen Pharma, Rawat conducted on 25-11-2019 & 12-12-2019 concluded that the panel unanimously recommended the renewal of DML
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1120.	**Name and address of manufacturer / Applicant**	**M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan**
	Brand Name + Dosage Form + Strength	Empazin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……. 10mg
	Diary No. Date of R& I & fee	Dy. No 13776 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Empoli Tablet by Sami
	GMP status	Panel inspection for renewal of DML of M/s. Biogen Pharma, Rawat conducted on 25-11-2019 & 12-12-2019 concluded that the panel unanimously recommended the renewal of DML
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1121.	**Name and address of manufacturer / Applicant**	**M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Emplin Tablet 25mg
	Composition	Each Film Coated Tablet Contains:

		Empagliflozin ……. 25mg
	Diary No. Date of R& I & fee	Dy.No 14585 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Empoli Tablet by Sami
	GMP status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1122	**Name and address of manufacturer / Applicant**	**M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Emplin Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……. 10mg
	Diary No. Date of R& I & fee	Dy.No 14584 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Empoli Tablet by Sami
	GMP status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1123	**Name and address of manufacturer / Applicant**	**M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Emplin M Tablet 12.5/500mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin…….500mg
	Diary No. Date of R& I & fee	Dy.No 14586 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved

	Me-too status (with strength and dosage form)	Diajard-M Tablet by Highnoon
	GMP status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1124.	**Name and address of manufacturer / Applicant**	**M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Emplin M Tablet 12.5/850mg
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin……..850mg
	Diary No. Date of R& I & fee	Dy.No 14587 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Diajard-M Tablet by Highnoon
	GMP status	The firm was inspected on 10-07-2019 and conclusion of inspection was: Keeping in view the above it may be concluded that M/s Linta Pharmaceuticals is operating at acceptable level of GMP standard.
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1125.	**Name and address of manufacturer / Applicant**	**M/s Fassgen Pharmaceuticals Plot No. 67/1-A, Phase-III, Industral Estate, Hattar**
	Brand Name + Dosage Form + Strength	Emzin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin ……. 10mg
	Diary No. Date of R& I & fee	Dy.No 15892 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Empoli Tablet by Sami
	GMP status	
	Remarks of the Evaluator [II]:	

	• Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1126.	**Name and address of manufacturer / Applicant**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Brand Name + Dosage Form + Strength	Empazin Plus SR 12.5/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl (Sustained Release)…1000mg
	Diary No. Date of R& I & fee	Dy.No 14965 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Xenglu-Met XR Tablet by Hilton
	GMP status	
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1127.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name + Dosage Form + Strength	Dexozol 60mg Tablet
	Composition	Each Capsule Contains: Dexlansoprazole…….60mg
	Diary No. Date of R& I & fee	Dy.No 14688 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1128.	**Name and address of manufacturer / Applicant**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Dexizol 60mg Capsule
	Composition	Each Delayed Release Capsule Contains: Dexlansoprazole…….60mg

	Diary No. Date of R& I & fee	Dy. No 16436 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1129.	**Name and address of manufacturer / Applicant**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Dexizol 30mg Capsule
	Composition	Each Delayed Release Capsule Contains: Dexlansoprazole…….30mg
	Diary No. Date of R& I & fee	Dy. No 16436 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1130.	**Name and address of manufacturer / Applicant**	**M/s Hamaz Pharmaceuticals Pvt Ltd .Business City Plaza, Hall # 1, 2nd Floor, Bosan Road, Multan, Pakistan**
	Brand Name + Dosage Form + Strength	Mazodex Capsule 60mg
	Composition	Each Capsule Contains: Dexlansoprazole……..60mg
	Diary No. Date of R& I & fee	Dy.No 15721 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II:	

	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1131.	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Dexlansip 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole……..30mg
	Diary No. Date of R& I & fee	Dy.No 13513 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1132.	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Dexlansip 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole……..60mg
	Diary No. Date of R& I & fee	Dy.No 13514 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	

1133.	**Name and address of manufacturer / Applicant**	**M/s Libra Pvt Ltd 77-Peshawar Industrial Estate, Hayatabad Peshawar**
	Brand Name + Dosage Form + Strength	Lanxodex DR 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy.No 16900 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1134.	**Name and address of manufacturer / Applicant**	**M/s Libra Pvt Ltd 77-Peshawar Industrial Estate, Hayatabad Peshawar**
	Brand Name + Dosage Form + Strength	Lanxodex DR 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy.No 16901 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1135.	**Name and address of manufacturer / Applicant**	**M/s Marvi Pharmaceuticals. Plot No. 70, Sector 24, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Dexazolan 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Pellets Eq. To Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy.No 13718 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5

	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Revise your label claim as per the reference product along with submission of requisite fee as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1136.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Dexlan 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole As Dexlansoprazole Delayed Release Pellets…60mg
	Diary No. Date of R& I & fee	Dy.No 14184 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1137.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Dexlan 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole As Dexlansoprazole Delayed Release Pellets…30mg
	Diary No. Date of R& I & fee	Dy.No 14183 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II:	

	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1138.	**Name and address of manufacturer / Applicant**	**M/s Medicon Pharmaceuticals Pvt Ltd. Industrial Estate, Jamrud Road, Peshawar, Pakistan**
	Brand Name + Dosage Form + Strength	Dexazole 60mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayaed Release Pellets Eq To Dexlansoprazole…….60mg
	Diary No. Date of R& I & fee	Dy.No 13464 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1139.	**Name and address of manufacturer / Applicant**	**M/s Medicon Pharmaceuticals Pvt Ltd. Industrial Estate, Jamrud Road, Peshawar, Pakistan**
	Brand Name + Dosage Form + Strength	Dexazole 30mg Capsule
	Composition	Each Capsule Contains: Dexlansoprazole Dual Delayaed Release Pellets Eq To Dexlansoprazole…….30mg
	Diary No. Date of R& I & fee	Dy.No 13465 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Razodex Capsule of Getz
	GMP status	
	Remarks of the Evaluator II: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1140.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Apicure 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Apixaban…….5mg

	Diary No. Date of R& I & fee	Dy.No 16345 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Apiban tablet of M/s Highnoon.
	GMP status	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019.
	Remarks of the Evaluator [II]: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1141.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Apicure 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Apixaban…….2.5mg
	Diary No. Date of R& I & fee	Dy.No 16347 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form 5
	Finished product Specifications	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Apiban tablet of M/s Highnoon.
	GMP status	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019.
	Remarks of the Evaluator [II]: • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. • Latest GMP inspection report conducted within a period of last three years.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1142.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Adcon 150mg Capsule
	Composition	Each Capsule Contains: Fluconazole……150mg
	Diary No. Date of R& I & fee	Dy.No 16999 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azocan 150 of M/s FDC International Ltd. approved by MHRA of UK
	Me-too status (with strength and dosage form)	Fantizol Capsule by M/ Apex Karachi. (Reg#073551)

	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised drug product specifications as per BP monograph, without submission of fee.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1143.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Lamisil 125mg Tablet
	Composition	Each Film Coated Tablet Contains: Terbinafine HCl…..…125mg
	Diary No. Date of R& I & fee	Dy. No 16042 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	1 x 10's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mycoderm 125mg Tablet by M/s Nabiqasim Karachi. (Reg.# 081045)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring label claim in terms of Terbinafine, and dosage form as uncoated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 111158062608. "Each Tablet Contains: Terbinafine as HCl…..…125mg"	
	Decision: Approve as per following label claim: **"Each Tablet Contains:** **Terbinafine as HCl…..…125mg"**	
1144.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Cozar 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…25mg
	Diary No. Date of R& I & fee	Dy.No 16043 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Angiotensin II antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bepsar 25mg Tablet by M/s Nabiqasim Karachi. (Reg.# 033384)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	

	Decision: Approved.	
1145.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Ancid 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Flurbiprofen……100mg
	Diary No. Date of R& I & fee	Dy.No 16034 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Strefen Tablets of Healers Pharmaceuticals (Reg.# 069733)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised drug product specifications as per USP monograph, without submission of fee.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1146.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Zanaflex 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Tizanidine Hydrochloride…4mg
	Diary No. Date of R& I & fee	Dy.No 16037 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Centrally acting agent; muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	SN Skelax 4 mg Tablets by M/s SNB Pharma (Pvt) Ltd. (Reg#078413)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring label claim in terms of Tizanidine, and dosage form as uncoated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 1604826473. "Each Tablet Contains: Tizanidine as HCl…..…125mg"	
	Decision: Approved as per following label claim: **"Each Tablet Contains:** **Tizanidine as HCl…..…125mg"**	
1147.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**

	Brand Name + Dosage Form + Strength	Cozar mg Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg
	Diary No. Date of R& I & fee	Dy.No 16045 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Angiotensin II antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bepsar 25mg Tablet by M/s Nabiqasim Karachi. (Reg.# 033384)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II:	
	Decision: Approved.	
1148.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Deflux 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Domperidone…10mg
	Diary No. Date of R& I & fee	Dy.No 16035 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Peripheral dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength and dosage form)	Epodom 10mg Tablets of M/s Atlantic Pharmaceutical (Pvt.) Ltd, (Reg.# 062326)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1149.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Hazar 25/100mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydrochlorothiazide…25mg Losartan Potassium…100mg
	Diary No. Date of R& I & fee	Dy.No 16040 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Angiotensin II antagonists and diuretics
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Co-Eziday Tablets of M/s Werrick Pharmaceutical
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22

	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1150.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Zanaflex 2mg Tablet
	Composition	Each Film Coated Tablet Contains: Tizanidine Hydrochloride…2mg
	Diary No. Date of R& I & fee	Dy.No 16037 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Centrally acting agent; muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	SN Skelax 4 mg Tablets by M/s SNB Pharma (Pvt) Ltd.
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring label claim in terms of Tizanidine, and dosage form as uncoated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 27845250049. "Each Tablet Contains: Tizanidine as HCl…..…125mg"	
	Decision: Approved as per following label claim: **"Each Tablet Contains:** **Tizanidine as HCl…..…125mg"**	
1151.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Icon 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole……100mg
	Diary No. Date of R& I & fee	Dy.No 16050 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-fungal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mukil Capsule 100mg of M/s. Dyson Research Laboratories (Pvt) Ltd (Reg.# 055356)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva.	
	Decision: Approved. Firm shall submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-IVA before issuance of registration letter.	
1152.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Metzone 5mg Tablet

	Composition	Each Film Coated Tablet Contains: Metolazone……5mg
	Diary No. Date of R& I & fee	Dy.No 16044 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Sulfonamides
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Metxone tablet 5mg (Reg.# 090699) of M/s Genome
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1153.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Sensipar 30mg Tablet
	Composition	Each Film Coated Tablet Contains: Cinacalcet…30mg
	Diary No. Date of R& I & fee	Dy.No 16048 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-parathyroid agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1154.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Sensipar 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Cinacalcet…60mg
	Diary No. Date of R& I & fee	Dy.No 16049 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-parathyroid agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	

	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB within 6 months.	
1155.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Crestor 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin As Calcium…5mg
	Diary No. Date of R& I & fee	Dy.No 17001 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Rosat Tablets 5 mg by M/s Genera Pharma. (Reg.# 069984)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised drug product specifications as per USP monograph, without submission of fee.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1156.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Crestor 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin As Calcium…10mg
	Diary No. Date of R& I & fee	Dy.No 17002 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Xplendid Tablets by M/s Pharmevo
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised drug product specifications as per USP monograph, without submission of fee.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1157.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Crestor 20mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Rosuvastatin As Calcium…20mg
	Diary No. Date of R& I & fee	Dy.No 17003 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Xplendid Tablets by M/s Pharmevo
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised drug product specifications as per USP monograph, without submission of fee.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1158.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Vildamet 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy. No 17006 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Galmet 50mg/1000mg Table M/s Vision Pharma (Ref# 081907)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1159.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Vildamet 50/1000 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy. No 17006 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Galmet 50mg/1000mg Table M/s Vision Pharma (Ref# 081907)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1160.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Vildamet 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy. No 17005 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Galmet 50mg/850mg Table M/s Vision Pharma (Ref# 081906)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1161.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Vildamet 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 17004 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Galmet 50mg/500mg Table M/s Vision Pharma (Ref# 081905)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1162.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Vildaglip 50mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Vildagliptin……50mg
	Diary No. Date of R& I & fee	Dy.No 16992 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Galza Table M/s CCL Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1163.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Adin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Loratadine…….10mg
	Diary No. Date of R& I & fee	Dy. No 16039 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Senergy OD 10mg tablet, Highnoon Labs. Reg. No. 017672.
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring the dosage form as uncoated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 33347719539 along with change of specifications to USP "Each Tablet Contains: Loratadine…..…10mg"	
	Decision: Approved with USP specifications as per following label claim: "Each Tablet Contains: Loratadine…..…10mg"	
1164.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Adin 5mg/5ml Oral Solution
	Composition	Each 5ml Contains: Loratadine…5mg
	Diary No. Date of R& I & fee	Dy.No 16040 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Victrin 1mg/ml Liquid Syrup by M/s Barret Hodgson (Reg#027277)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised drug product specifications as per USP monograph, without submission of fee.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1165.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Arcos 60mg Tablet
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy .No 16038 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Etoria 60mg Table of M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080818)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1166.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Estin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Dy. No 16987 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANMS of France
	Me-too status (with strength and dosage form)	Clubex 10mg Tablets of M/s Welmark Pharmaceuticals. (Reg.# 056446)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Firm has applied in-house specifications whereas Pharmacopoeial monograph is available for applied formulation. • Firm has submitted revised drug product specifications as per JP monograph, without submission of fee.	

	Decision: Approved with JP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1167.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Prevacid 30mg Capsule
	Composition	Each Capsule Contains: Lansoprazole Enteric Coated Pellets Eq. To Lansoprazole…….30mg
	Diary No. Date of R& I & fee	Dy.No 16988 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Proton pump inhibitor.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 7's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Leazole 30mg Capsules of M/s Leads Pharma (Pvt.) Ltd. (Reg.#035891)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-IVa. • Firm has submitted relevant documents for source of pellets from M/s Vision pharmaceuticals.	
	Decision: Approved.	
1168.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Haemfil 100mg/5ml Syrup
	Composition	Each 5ml Contains: Polysaccharide Iron Complex……100mg
	Diary No. Date of R& I & fee	Dy.No 16990 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-anaemic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not applicable
	Me-too status (with strength and dosage form)	Iron- Sac Syrup of M/s Lowitt Pharmaceutical, Peshawar 056655
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Submit revised label claim declaring the strength in terms of the elemental Iron alongwith relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 306977295 Each 5ml Contains: Polysaccharide Iron Complex eq. to elemental Iron ……100mg	
	Decision: Approved with innovator's specifications as per following label claim: **Each 5ml Contains:** **Polysaccharide Iron Complex eq. to elemental Iron ……100mg**	
1169.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Malafan 80/480 mg Tablet

	Composition	Each Film Coated Tablet Contains: Artemether …… 80mg Lumefantrine …..… 480mg
	Diary No. Date of R& I & fee	Dy.No 16989 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	WHO prequalified formulation
	Me-too status (with strength and dosage form)	Artem -DS Plus Tablets 80/480 of M/s Hilton Pharma, Karachi (Reg.# 066843)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]: • Reference product is available as uncoated tablet, whereas firm has applied for Film coated tablet hence submit revised label claim declaring the dosage form as uncoated tablet, alongwith relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under along with submission of fee of Rs. 30,000/- vide deposit slip# 55567755682 Each Tablet Contains: Artemether……80mg Lumefantrine…..…480mg	
	Decision: Approved as per following label claim: **"Each Tablet Contains:** **Artemether …… 80mg** **Lumefantrine …..… 480mg"**	
1170.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Genac-K 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac Potassium……50mg
	Diary No. Date of R& I & fee	Dy.No 16993 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antirheumatic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dicota 50 Tablet of M/s Linz Karachi, (Reg.# 073524)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1171.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt.) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name + Dosage Form + Strength	Irosoft Chewable Tablet
	Composition	Each Chewable Tablet Contains: Iron III Hydroxy Polymaltose Complex Eq. To Elemental Iron ……100mg Folic Acid …… 0.35mg
	Diary No. Date of R& I & fee	Dy. No 16991 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-anaemic
	Type of Form	Form-5

	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Ipomalt -F Tablets of M/s Rock Pharmaceutical Laboratories (Pvt) Ltd. (Reg.# 077301)
	GMP status	GMP certificate issued on basis of inspection conducted on 20-10-22
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1172.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Mevodip V 10/160mg Table
	Composition	Each Tablet Contains: Amlodipine Besylate …..…10mg Valsartan…….160mg
	Diary No. Date of R& I & fee	Dy.No 16784 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Valpine Tablets 10/160mg by M/s Fassgen Pharmaceuticals, (Reg. No. 073303)
	GMP status	--
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved. Registration letter will be issued upon submission of following; • **Revised label claim as per innovator product, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.** • **Latest GMP inspection report conducted within last three years.**	
1173.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Dexifen 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen……200mg
	Diary No. Date of R& I & fee	Dy. No 15983 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dexipin 200mg tablet of AGP
	GMP status	--
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-	

	B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
1174.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Dexifen 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen……300mg
	Diary No. Date of R& I & fee	Dy.No 15984 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dexipin tablet of AGP
	GMP status	--
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
1175.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Dexifen 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen……400mg
	Diary No. Date of R& I & fee	Dy.No 15985 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dexipin tablet of AGP
	GMP status	--
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
1176.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Soval 250mg Tablet
	Composition	Each Tablet Contains: Divalproex Sodium Eq. To Valproic Acid…250mg
	Diary No. Date of R& I & fee	Dy.No 15989 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Divanza tablet of m/s Hiranis
	GMP status	--
	Remarks of the Evaluator II: Clarification shall be submitted whether applied formulation is delayed release/ extended release or otherwise, along with relevant annexures of Form 5.	
	Decision: Deferred for clarification whether applied formulation is delayed release/ extended release or otherwise, along with submission of relevant annexures of Form 5.	
1177.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Soval 500mg Tablet
	Composition	Each Tablet Contains: Divalproex Sodium Eq. To Valproic Acid…500mg
	Diary No. Date of R& I & fee	Dy.No 15988 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Divanza tablet of m/s Hiranis
	GMP status	--
	Remarks of the Evaluator II: Clarification shall be submitted whether applied formulation is delayed release/ extended release or otherwise, along with relevant annexures of Form 5.	
	Decision: Deferred for clarification whether applied formulation is delayed release/ extended release or otherwise, along with submission of relevant annexures of Form 5.	
1178.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Isotran 10mg Capsule
	Composition	Each Capsule Contains: Isotretinoin…10mg
	Diary No. Date of R& I & fee	Dy.No 15979 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Retinoids
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Acnewin Capsule 10mg of Wnsfield Pharmaceuticals (Reg.# 064334)
	GMP status	--
	Remarks of the Evaluator II: • Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility. • In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.	
	Decision: Deferred for following: • **Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility.**	

	• **In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.**	
1179.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Isotran 20mg Capsule
	Composition	Each Capsule Contains: Isotretinoin…20mg
	Diary No. Date of R& I & fee	Dy.No 15980 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Retinoids
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Acnewin Capsule 20mg of Wnsfield Pharmaceuticals (Reg.# 064335)
	GMP status	--
	Remarks of the Evaluator II: • Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility. • In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.	
	Decision: Deferred for following: • **Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility.** • **In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.**	
1180.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Mesal 800mg Tablet
	Composition	Each Modified Release Tablet Contains: Mesalazine…800mg
	Diary No. Date of R& I & fee	Dy.No 15981 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Asacol tablets approved by MHRA of UK
	Me-too status (with strength and dosage form)	Glepib MR tablets of Martin Dow
	GMP status	--
	Remarks of the Evaluator II:	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years.	
1181.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Mesal 400mg Tablet
	Composition	Each Modified Release Tablet Contains: Mesalazine…400mg

	Diary No. Date of R& I & fee	Dy.No 15982 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Asacol tablets approved by MHRA of UK
	Me-too status (with strength and dosage form)	Glepib MR tablets of Martin Dow
	GMP status	--
	Remarks of the Evaluator [II]:	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1182.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Patdol 325/37.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol…325mg Tramadol HCl…37.5mg
	Diary No. Date of R& I & fee	Dy.No 15990 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Analgesic/Antipyretic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Distalgesic Tablet by M/s Atco Lab. Karachi. (Reg#073865)
	GMP status	--
	Remarks of the Evaluator [II]:	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1183.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Seraline 100mg Tbalet
	Composition	Each Tablet Contains: Sertraline As HCl…….100mg
	Diary No. Date of R& I & fee	Dy.No 15976 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	SSRI
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Yesme Tablet by M/s Metro Pharmaceuticals, Islamabad.
	GMP status	--
	Remarks of the Evaluator [II]: • Submit revised composition for film coated tablet as per innovator product, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved. Firm shall submit revised composition for film coated tablet as per innovator product, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 as well as latest GMP inspection report conducted within last three years before issuance of registration letter.	

1184.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Seraline 50mg Tbalet
	Composition	Each Tablet Contains: Sertraline As HCl…….50mg
	Diary No. Date of R& I & fee	Dy.No 15975 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	SSRI
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Yesme Tablet 50mg by M/s Metro Pharmaceuticals, Islamabad. (Reg.#081674)
	GMP status	--
	Remarks of the Evaluator [II]: • Submit revised composition for film coated tablet as per innovator product, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved. Firm shall submit revised composition for film coated tablet as per innovator product, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 as well as latest GMP inspection report conducted within last three years before issuance of registration letter.	
1185.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Metosit Tablet 50/500mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin As Phospate Monohydrate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 15987 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (with strength and dosage form)	Treviamet Tablet of M/s Getz Pharma Karachi.
	GMP status	--
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit f latest GMP inspection report conducted within last three years before issuance of registration letter.	
1186.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Metosit Tablet 50/1000mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin As Phospate Monohydrate…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy.No 15986 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (with strength and dosage form)	Treviamet Tablet of M/s Getz Pharma Karachi.
	GMP status	--
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit f latest GMP inspection report conducted within last three years before issuance of registration letter.	
1187.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Artist 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…….80mg
	Diary No. Date of R& I & fee	Dy.No 15978 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MICARDIS tablets USFDA Approved
	Me-too status (with strength and dosage form)	Telmi tablets by M/s Crystolite Pharmaceuticals
	GMP status	--
	Remarks of the Evaluator II:	
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1188.	**Name and address of manufacturer / Applicant**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Brand Name + Dosage Form + Strength	Artist 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan…….40mg
	Diary No. Date of R& I & fee	Dy.No 15978 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MICARDIS tablets USFDA Approved
	Me-too status (with strength and dosage form)	Telmi tablets by M/s Crystolite Pharmaceuticals
	GMP status	--
	Remarks of the Evaluator II:	
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1189.	**Name and address of manufacturer / Applicant**	**M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k**
	Brand Name + Dosage Form + Strength	Prloid Table 5mg
	Composition	Each Tablet Contains: Procyclidine Hcl…5mg
	Diary No. Date of R& I & fee	Dy.No 14353 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticholinergic
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Proclidine Tablets of M/s Shaheen Pharmaceuticals, 3Km Murghzar Road Saidu Sharif, Swat. (Reg.# 041018)
	GMP status	cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1190.	**Name and address of manufacturer / Applicant**	**M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k**
	Brand Name + Dosage Form + Strength	Prox CR Tablet
	Composition	Each Enteric Film Coated Controlled Release Tablet Contains: Paroxetine HCl……25mg
	Diary No. Date of R& I & fee	Dy.No 14356 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Deroxat CR tablet by Global Pharma
	GMP status	cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator [II]:	
	Decision: Approved. Firm shall submit revised label claim as per innovator product declaring the label claim in terms of Paroxetine base along with fee of Rs. 30,000/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1191.	**Name and address of manufacturer / Applicant**	**M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k**
	Brand Name + Dosage Form + Strength	Estra Plus Tablet 2/2mg
	Composition	Each Blister Pack Contains: 11 White Tablet Contains: Estradiol Valerate…2mg 11 Brown Tablet Contains: Estradiol Valerate…2mg Cyproterone…1mg
	Diary No. Date of R& I & fee	Dy.No 14401 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Climen by Bayer Schering Pharma AG Germany
	Me-too status (with strength and dosage form)	Climen by Bayer Health Care (Reg. No. 018207)
	GMP status	cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator [II]: Submit evidence of approval of required manufacturing facility of Tablet (steroidal hormone) section form Central Licensing Board. Submit evidence of availability of "co-blistering facility".	
	Decision: Deferred for review of formulation for requirement of "co-blistering" of two different tablets as per innovator product.	

1192.	**Name and address of manufacturer / Applicant**	**M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, K.P.K**
	Brand Name + Dosage Form + Strength	Cefodox 100mg/5ml
	Composition	Each 5ml Reconstituted Suspension Contains: Cefpodoxime Proxetil…100mg
	Diary No. Date of R& I & fee	Dy.No 14364 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti biotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Verpodoxine Dry Suspension by M/s Florence farma, Reg. No. 49247
	GMP status	cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1193.	**Name and address of manufacturer / Applicant**	**M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k**
	Brand Name + Dosage Form + Strength	Co Besart Tablet 300/25mg
	Composition	Each Film Coated Tablet Contains: Irbesartan …300mg Hydrochlorothiazide…….25mg
	Diary No. Date of R& I & fee	Dy.No 14379 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Irbest Plus Tablets of M/s. Highnoon Laboratories
	GMP status	cGMP certificate on the basis of Evaluation conducted on 06-04-2022
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1194.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name + Dosage Form + Strength	Amlov Hct Tablet 10/160/12.5mg
	Composition	Each Tablet Contains: Amlodipine…….10mg Valsartan……160mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy. No 14669 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	Sofvasc –HCT Tablet of Wilson's Pharmaceuticals, 387-388, I-9, Sector, Industrial Area, Islamabad. (Reg.# 077749)
	GMP status	GMP inspection dated 26-09-2019, the compliance level is rated as satisfactory.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring the salt form of Amlodipine and dosage form as film coated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Submit latest GMP inspection report conducted within last three years.	
	Decision: Registration Board deferred the case for following: • **Submission of reply to the above cited shortcomings within six months.** • **Verification of validity status of DML from Licensing Division.**	
1195.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name + Dosage Form + Strength	Amlov HCT Tablet 10/160/25mg
	Composition	Each Tablet Contains: Amlodipine…….10mg Valsartan……160mg Hydrochlorothiazide…….25mg
	Diary No. Date of R& I & fee	Dy.No 14668 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Sofvasc –HCT Tablet of Wilson's Pharmaceuticals
	GMP status	GMP inspection dated 26-09-2019, the compliance level is rated as satisfactory.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring the salt form of Amlodipine and dosage form as film coated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Submit latest GMP inspection report conducted within last three years.	
	Decision: Registration Board deferred the case for following: • **Submission of reply to the above cited shortcomings within six months.** • **Verification of validity status of DML from Licensing Division.**	
1196.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name + Dosage Form + Strength	Amlov HCt Tablet 5/160/12.5mg
	Composition	Each Tablet Contains: Amlodipine…….5mg Valsartan……160mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy.No 14668 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Sofvasc –HCT Tablet of Wilson's Pharmaceuticals
	GMP status	GMP inspection dated 26-09-2019, the compliance level is rated

		as satisfactory.
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring the salt form of Amlodipine and dosage form as film coated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Submit latest GMP inspection report conducted within last three years.	
	Decision: Registration Board deferred the case for following: • **Submission of reply to the above cited shortcomings within six months.** • **Verification of validity status of DML from Licensing Division.**	
1197.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals. A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name + Dosage Form + Strength	Amlov HCt Tablet 5/160/25mg
	Composition	Each Tablet Contains: Amlodipine…….5mg Valsartan……160mg Hydrochlorothiazide…….25mg
	Diary No. Date of R& I & fee	Dy.No 14668 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Sofvasc –HCT Tablet of Wilson's Pharmaceuticals
	GMP status	GMP inspection dated 26-09-2019, the compliance level is rated as satisfactory.
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring the salt form of Amlodipine and dosage form as film coated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Submit latest GMP inspection report conducted within last three years.	
	Decision: Registration Board deferred the case for following: • **Submission of reply to the above cited shortcomings within six months.** • **Verification of validity status of DML from Licensing Division.**	
1198.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	FXN Tablet 180mg
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…..…180mg
	Diary No. Date of R& I & fee	Dy. No 14696 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Fexokure Tablets 180mg. of M/s English Pharm (Reg.# 052411)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Submit reference for drug product specifications.	

	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1199.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Orphesic Forte 650/50mg
	Composition	Each Tablet Contains: Paracetamol…..…650mg Orphenadrine Citrate…….50mg
	Diary No. Date of R& I & fee	Dy. No 14697 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Narcotic analgesic combination
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Orthoflex-D 50mg Tablet of M/s Noa Hemis Karachi (Reg.# 075984)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]:	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1200.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Vortox 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine as Hydrobromide…..…20mg
	Diary No. Date of R& I & fee	Dy.No 16195 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Brintellix Tablets, M/s Lundbeck Pakistan (Pvt) Ltd., 40 T/4, Blessing Street, Block6, P.E.C.H.S, Karachi, Karachi
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB, in light of the notification No. 320-DRB/ 2022(PE&R) dated 17th October 2022.	
1201.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Vortox 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Vortioxetine as Hydrobromide…..…10mg
	Diary No. Date of R& I & fee	Dy.No 16194 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Brintellix Tablets, M/s Lundbeck Pakistan (Pvt) Ltd., 40 T/4, Blessing Street, Block6, P.E.C.H.S, Karachi, Karachi
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Deferred for submission of stability studies data as per checklist of 293rd meeting of DRB, in light of the notification No. 320-DRB/ 2022(PE&R) dated 17th October 2022.	
1202.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Atasart 10mg Tablet
	Composition	Each Tablet Contains: Baclofen…….10mg
	Diary No. Date of R& I & fee	Dy.No 16191 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Skeletal muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Beclotab Tablets by M/s Werrick Pharmaceuticals. (Reg#026758)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1203.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Ancotin 20mg Capsule
	Composition	Each Capsule Contains: Isotretinoin…….20mg
	Diary No. Date of R& I & fee	Dy.No 16190 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Retinoids
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Oratane capsule by M/s Crysolite
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Clarification shall be submitted for applied dosage form whether hard Gelatin capsule or soft Gelatin capsule.	
	Decision: Deferred for following: • **Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility.** • **In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.**	

1204.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Oxytrol 3mg Tbalet
	Composition	Each Tablet Contains: Oxybutynin HCl…..…3mg
	Diary No. Date of R& I & fee	Dy.No 16197 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Bunin tablets of M/s Libra Pharmaceuticals (Reg.# 030317)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. • Reference for drug product specifications.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
1205.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Maxate 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Methotrexate…..…10mg
	Diary No. Date of R& I & fee	Dy. No 16193 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Methotrexate tablet 10mg of M/s Pak China International (Reg# 066009)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section", from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. • Evidence of approval of applied formulation as "film coated tablet" in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Registration Board rejected the application since firm does not have approval for required manufacturing facility of "Cytotoxic/Oncology Tablet section".	
1206.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Maxate 2.5mg Tablet

	Composition	Each Film Coated Tablet Contains: Methotrexate…..…2.5mg
	Diary No. Date of R& I & fee	Dy.No 16192 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Methotrexate 2.5mg by PAK CHINA INTERNATIONAL (Reg #066007)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section", from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. • Evidence of approval of applied formulation as "film coated tablet" in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Registration Board rejected the application since firm does not have approval for required manufacturing facility of "Cytotoxic/Oncology Tablet section".	
1207.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Motrin 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Ibuprofen…….200mg
	Diary No. Date of R& I & fee	Dy. No 15188 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Suprofen Tablet 200mg of M/s Kohs Hyderabad (Reg.# 070618)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Submit reference for drug product specifications.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1208.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Motrin 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Ibuprofen…….400mg
	Diary No. Date of R& I & fee	Dy. No 15187 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Suprofen Tablet 400mg of M/s Kohs Hyderabad (Reg.# 070619)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Submit reference for drug product specifications.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1209.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Spasfree 5mg Tablet
	Composition	Each Tablet Contains: Hyoscine Butylbromide…5mg
	Diary No. Date of R& I & fee	Dy. No 15193 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
1210.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Ursolox 250mg suspension
	Composition	Each 5ml Contains: Ursodeoxycholic Acid…..…250mg
	Diary No. Date of R& I & fee	Dy.No 15192 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticholelithic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Ursodol suspension of M/s OBS Pharma (Reg.# 085632)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. • Reference for drug product specifications shall be submitted.	

	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
1211.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Ursolox 250mg capsule
	Composition	Each Capsule Contains: Ursodeoxycholic Acid…250mg
	Diary No. Date of R& I & fee	Dy.No 15194 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticholelithic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength and dosage form)	Rivsa 250mg capsule of M/s martin Dow (Reg.# 082263)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Reference for drug product specifications shall be submitted.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1212.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Ursolox 500mg capsule
	Composition	Each Capsule Contains: Ursodeoxycholic Acid…..500mg
	Diary No. Date of R& I & fee	Dy.No 15190 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticholelithic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength and dosage form)	Rivsa 500mg capsule of M/s martin Dow (Reg.# 082264)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Reference for drug product specifications shall be submitted.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1213.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Prometa 10mg Tablet
	Composition	Each Tablet Contains: Metoclopramide HCl …… 10mg
	Diary No. Date of R& I & fee	Dy. No 15185 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-dopaminergic

	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Faclomide 10mg Tablets of M/s Farm Aid Group
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved. Firm shall submit revised label claim as per innovator product, declaring the applied strength in terms of Metoclopramide base, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 before issuance of registration letter.	
1214.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Prometa 1mg Drops
	Composition	Each ml Contains: Metoclopramide HCl…….1mg
	Diary No. Date of R& I & fee	Dy.No 15184 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-dopaminergic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not available in drops presentation
	Me-too status (with strength and dosage form)	Not available in drops presentation
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Registration Board rejected the registration application since applied formulation is not approved by any reference reg ulatory authority in dosage form of "Drops", also the firm has applied separate application of same formulation in syrup dosage form.	
1215.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Spasfree plus 10/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Hyoscine Butylbromide…10mg Paracetamol…500mg
	Diary No. Date of R& I & fee	Dy. No 15190 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Buscopan Plus tablet approved by BFARM of Germany
	Me-too status (with strength and dosage form)	Spasmed Plus Tablets of M/s Genome (Reg.#068384)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.

	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1216.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Spasfree 5mg/5ml Syrup
	Composition	Each 5ml Contains: Hyoscine Butylbromide…….5mg
	Diary No. Date of R& I & fee	Dy.No 15191 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Spacure Syrup of m/s Safe Pharmaceuticals (Reg.# 070564)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1217.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Prometa 5MG/5ML Syrup
	Composition	Each 5ml Contains: Metoclopramide HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 15183 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mexoram syrup of M/s Meditech pharmaceuticals. (Reg.#046388)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II:	
	Decision: Approved. Firm shall submit revised label claim as per innovator product declaring the monohydrate form of Metoclopramide hydrochloride and quantity of active ingredient in terms of the equivalent amount of anhydrous metoclopramide hydrochloride with fee of Rs. 30,000/- for correction/pre-approval change in composition as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1218.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Densium 2g Sachet
	Composition	Each Sachet Contains: Strontium Ranelate ……. 2gm
	Diary No. Date of R& I & fee	Dy.No 16196 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-osteoporosis

	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Strontium ranelate Aristo 2 g granules for oral suspension by M/s Aristo Pharma GmbH Wallenroder Straße 8-10 13435 Berlin Germany, MHRA Approved.
	Me-too status (with strength and dosage form)	ONITA SACHET by M/s PHARM-EVO (PVT) LTD, (Reg. No. 057746)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1219.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Oxytrol 5mg Tbalet
	Composition	Each Tablet Contains: Oxybutynin HCl…..…5mg
	Diary No. Date of R& I & fee	Dy.No 16198 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Bunin 3mg tablets of M/s Libra Pharmaceuticals
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. • Reference for drug product specifications.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
1220.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Motrin suspension 100mg/5ml
	Composition	Each 5ml Contains: Ibuprofen…400mg
	Diary No. Date of R& I & fee	Dy.No 15189 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-Pyretic, Analgesic & Anti-Inflammatory
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Brufen suspension of M/s Abbott

	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Submit reference for drug product specifications.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1221.	**Name and address of manufacturer / Applicant**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Motrin DS suspension 200mg/5ml
	Composition	Each 5ml Contains: Ibuprofen…200mg
	Diary No. Date of R& I & fee	Dy.No 15186 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-Pyretic, Analgesic & Anti-Inflammatory
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Brufen suspension of M/s Abbott
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Submit reference for drug product specifications.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1222.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Serazone 1gm IM/IV Injection
	Composition	Each Vial Contains: Cefoperazone Sodium Eq. To Cefoperazone…500mg Sulbactam Sodium Eq. To Sulbactam…500mg
	Diary No. Date of R& I & fee	Dy.No 14160 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA-Japan
	Me-too status (with strength and dosage form)	2Sum Injection 1g of M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1223.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Claricum 500mg Tablet
	Composition	Each film coated tablet contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Dy. No 14168 dated 07-03-2019 Rs.20,000/- dated 07-03-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BIAXIN of M/s Abbvie approved by USFDA
	Me-too status (with strength and dosage form)	Klarinor 500 mg Tablets by M/s Nortech Pharmaceuticals (Pvt) Ltd (Reg#077970)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1224.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	MB Mox 250mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Amoxicillin Trihydrate Eq. To Amoxicillin…250mg
	Diary No. Date of R& I & fee	Dy.No 14168 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Oximox suspension by CSH
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1225.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Kerolac 30mg/ml Injection
	Composition	Each ml Contains: Ketorolac Tromethamine……30mg
	Diary No. Date of R& I & fee	Dy.No 14174 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	US-FDA Approved.
	Me-too status (with strength and dosage form)	Tromit Injection of Standpharm (Reg.# 049960)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]: • Submit reference for drug product specifications. • Firm has not mentioned terminal sterilization step in the manufacturing process. • Firm has submitted revised specifications as USP without submission of fee.	
	Decision: Deferred for clarification regarding method of sterilisation proposed for applied formulation along with fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	

1226.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Loratec 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine……..5mg
	Diary No. Date of R& I & fee	Dy.No 14185 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Desdine 5mg Tablet of M/s M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080821)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: • Submit reference for drug product specifications. • Firm has submitted revised specifications as USP without submission of fee.	
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1227.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Phenilate 10mg Tablet
	Composition	Each Tablet Contains: Methyl Phenidate as HCl…10mg
	Diary No. Date of R& I & fee	Dy. No 14163 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Centrally Acting Sympathomimetics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Phenilin tablets of M/s Dosaco Laboratories, Lahore Reg.no.024297
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under without submission of fee: Each Tablet Contains: Methyl Phenidate HCl…10mg	
	Decision: Approved with innovator's specifications as per following label claim: **"Each Tablet Contains:** **Methyl Phenidate HCl …… 10mg"** **Firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product composition as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1228.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	MB Mox 125mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Amoxicillin Trihydrate Eq. To Amoxicillin…125mg

	Diary No. Date of R& I & fee	Dy.No 14152 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Oximox suspension by CSH
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1229.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Moxilin 400mg Tablet
	Composition	Each film coated tablet contains: Moxifloxacin HCl As Moxifloxacin…..…400mg
	Diary No. Date of R& I & fee	Dy.No 14157 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Metoxim 400mg Tablet by M/s Foray Pharmaceutical
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1230.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Diclotim 75mg Tablet
	Composition	Each Tablet Contains: Diclofenac Potassium……75mg
	Diary No. Date of R& I & fee	Dy.No 14165 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Beflam 75mg Tablet by M/s Batala Pharmaceuticals Reg.#031128
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: In order to dispose of new applications of Diclofenac Potassium 75mg tablet, the Board requested Pharmacy Services Divison to intimate PE&R Division regarding provision of safety and efficacy studies approved bv any credible sources and shared by manufcaturers and if no such	

	studies are available than PMA will conduct safety and efficacy trials as per Bio study rules, 2017, as decided by Appellate Board in 162nd meeting.	
1231.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Ritant 40mg Capsule
	Composition	Each Capsule Contains: Aprepitant……..40mg
	Diary No. Date of R& I & fee	Dy.No 14158 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Piptant 40mg capsule by M/s Batala Pharmaceuticals Reg.#031128
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1232.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Reon 250mg
	Composition	Each Tablet Contains: Terbinafine HCl As Terbinafine……250mg
	Diary No. Date of R& I & fee	Dy.No 14155 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Neoterbin Tablets 250mg by M/s Neomedix Pharmaceuticals, Islamabad. (Reg.# 081411)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: Submit reference for drug product specifications. Firm has submitted revised specifications as USP without submission of fee.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1233.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Zerox 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam……8mg
	Diary No. Date of R& I & fee	Dy.No 14179 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-inflammatory and Antirheumatic Products
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	As per PRC

	Approval status of product in Reference Regulatory Authorities	Xefo 8mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
	Me-too status (with strength and dosage form)	Acabel Tablets 8mg, S.J & G Fazul Ellahie, Reg. No. 061604.
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1234	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Razepate 5mg Capsule
	Composition	Each Capsule Contains: Clorazepate Dipotassium…..…5mg
	Diary No. Date of R& I & fee	Dy.No 14177 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1235	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Asartin 50mg Tablet
	Composition	Each Tablet Contains: Losartan Potassium…….…50mg
	Diary No. Date of R& I & fee	Dy.No 14151 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	COZAAR® (losartan potassium) tablets Approved by USFDA with box warning.
	Me-too status (with strength and dosage form)	Losanta 50mg Tablet M/s Asian Continental (Pvt.) Ltd Karachi 057848
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	

	• Submit revised composition for film coated tablet as per innovator product, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised composition for film coated tablet without submission of fee.	
	Decision: Approved as per following label claim: **"Each film coated tablet contains:** **Losartan Potassium …… 50mg"** **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product dosage form to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance registration letter.**	
1236.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	MB Kanz 250mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Ciprofloxacin As HCl …… 250mg
	Diary No. Date of R& I & fee	Dy. No 14161 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status (with strength and dosage form)	Quash 250mg/5ml suspension of M/s Wilshire Laboratories Pvt. Ltd.
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: • Submit details for source of drug substance pellets alongwith, COA, GMP certificate and stability studies. • Details of the accompanying diluent for reconstitution shall be submitted along with the manufacturing area in which it will be produced. • Firm has submitted documents of source of pellets of Ciprofloxacin Taste masked pellets from M/s Vision Pharma.	
	Decision: Approved as per following label claim: **"Each 5ml of reconstituted suspension Contains:** **Ciprofloxacin …… 250mg"** • **Firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in salt form of drug substance, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance registration letter.**	
1237.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Cefadol 500mg Capsule
	Composition	Each Capsule Contains: Cefadroxil……500mg
	Diary No. Date of R& I & fee	Dy.No 14154 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Caredrox Capsule 500mg by M/s Bryon Pharmaceuticals (Reg#090694)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved as per following label claim: **"Each Capsule Contains:** **Cefadroxil as monohydrate……500mg"** • **Firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in salt form of drug substance, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance registration letter.**	
1238.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	C.Ferol 5mg IM Oral Injection
	Composition	Each ml Contains: Cholecalciferol…….…5mg
	Diary No. Date of R& I & fee	Dy.No 14156 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin D3 analogue
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1239.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Claricum 250mg Tablet
	Composition	Each film coated tablet contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Dy.No 14156 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BIAXIN of M/s Abbvie approved by USFDA
	Me-too status (with strength and dosage form)	Klarinor Tablets by M/s Nortech Pharmaceuticals (Pvt) Ltd
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1240.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Paratram Tablets

	Composition	Each Tablet Contains: Tramadol HCl …..… 37.5mg Paracetamol…….325mg
	Diary No. Date of R& I & fee	Dy.No 14176 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Analgesic/Opioid analogue
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ultracet by Janssen (USFDA)
	Me-too status (with strength and dosage form)	Distalgesic Tablets by Atco laboratories, Karachi (R. No. 073865)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring the dosage form as film coated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Frim has submitted revised composition for film coated tablet without submission of fee.	
	Decision: Approved as per following label claim: **Each film coated tablet contains:** **Tramadol HCl …..… 37.5mg** **Paracetamol ……. 325mg** • **Firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in the dosage form as film coated tablet as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 before issuance of registration letter.**	
1241.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Panticol Tablet
	Composition	"Each Tablet Contains: Paracetamol…….500mg Chlorpheniramine…….4mg Pseudoephedrine HCl……..60mg"
	Diary No. Date of R& I & fee	Dy.No 14159 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Analgesic/Antihistamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Panadol CF Tablet by GSK (Reg.# 013113)
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1242.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Dozin 40mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefpodoxime Proxetil……40mg

	Diary No. Date of R& I & fee	Dy.No 14181 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Third generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime 40mg/5ml granules for oral suspension by Milpharm Limited (MHRA)
	Me-too status (with strength and dosage form)	Xipodox 40mg /5ml by M/s. Vega Pharmaceuticals, Lahore
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under without submission of fee: "Each 5ml Contains: Cefpodoxime as Proxetil…….40mg"	
	Decision: Approved as per following label claim: **"Each 5ml Contains:** **Cefpodoxime as Proxetil…….40mg"** • **Firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in the composition as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 before issuance of registration letter.**	
1243.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Razepate 10mg Capsule
	Composition	Each Capsule Contains: Clorazepate Dipotassium…..…10mg
	Diary No. Date of R& I & fee	Dy.No 14178 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1244.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Evon 30mg Tablet

	Composition	Each Tablet Contains: Ephedrine HCl…..…30mg
	Diary No. Date of R& I & fee	Dy.No 14164 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Sympathomimetic agent
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bexelex 30mg tablet of M/s Berlex Lab (Reg.# 065979)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]: • Submit reference for drug product specifications. • Firm has submitted revised specifications as BP, without submission of fee.	
	Decision: Approved with BP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1245.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Cinamin 500mcg IM /IV Injection
	Composition	Each 2ml Contains: Cyanocobalamin…….500mcg
	Diary No. Date of R& I & fee	Dy.No 14173 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin b12
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1246.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Omodine 50mg IM/IV Injection
	Composition	Each 2ml Contains: Ranitidine HCl Eq. To Ranitidine…50mg
	Diary No. Date of R& I & fee	Dy.No 14172 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	H2-receptor antagonists
	Type of Form	Form 5
	Finished product Specifications	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Peplov Injection 50mg by M/s. Pulse Pharmaceuticals, (Reg#074175)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: • The applied formulation has been suspended by US FDA.	
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products.	
1247.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Viospan 200mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Cefixime As Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 14169 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SUPRAX 200mg/5ml Dry Powder Suspension USFDA Approved.
	Me-too status (with strength and dosage form)	Rofixime DS Suspension by SPL Pharmaceuticals (Pvt) Ltd, (Reg#45506)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1248.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Pritim 150mg Tablet
	Composition	Each Extended Release Tablet Contains: Itopride Hcl…150mg
	Diary No. Date of R& I & fee	Dy.No 14175 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Prokinetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Itoride SR Tablets of Amarant Karachi (Reg # 073484)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1249.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Silbet 50/500 mg Tablet

	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate…50mg Metformin HCl……500mg
	Diary No. Date of R& I & fee	Dy.No 14182 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-diabetic agent and oral hypoglycemic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sitamet tablet by M/s CCL Pharmaceuticals Pvt. Ltd.
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring the label claim for Sitagliptin phosphate monohydrate in terms of Sitagliptin base, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under without submission of fee: "Each Film Coated Tablet Contains: Sitagliptin as Phosphate monohydrate …50mg Metformin HCl……500mg"	
	Decision: Approved as per following label claim: **"Each Film Coated Tablet Contains:** **Sitagliptin as Phosphate monohydrate …50mg** **Metformin HCl……500mg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in salt form of drug substance as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1250.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Loratec 0.5mg/ml Syrup
	Composition	"Each ml Contains: Desloratadine……0.5mg"
	Diary No. Date of R& I & fee	Dy.No 14180 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aerius For Children Syrup desloratadine 2.5mg/5mL oral liquid bottle by M/s Bayer Australia Ltd (TGA approved)
	Me-too status (with strength and dosage form)	Desora 0.5mg/ml syrup by M/s Continental Pharma. (Reg.# 055192)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1251.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	MB Kanz 125mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Ciprofloxacin As HCl…125mg

	Diary No. Date of R& I & fee	Dy.No 14162 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Registration Board on the recommended dosage basis
	Me-too status (with strength and dosage form)	Quash 125mg/5ml suspension of M/s Wilshire Laboratories Pvt. Ltd.
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator II: • Submit details for source of drug substance pellets along with, COA, GMP certificate and stability studies. • Details of the accompanying diluent for reconstitution shall be submitted along with the manufacturing area in which it will be produced. • Firm has submitted source of pellets from M/s Vision Pharma.	
	Decision: Approved as per following label claim and diluent as per innovator drug product: **"Each 5ml of reconstituted suspension Contains:** **Ciprofloxacin …… 125mg"** • **Firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in salt form of drug substance, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance registration letter.**	
1252.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Metanium 15mg Capsule
	Composition	Each Capsule Contains: Temazepam……15mg
	Diary No. Date of R& I & fee	Dy.No 14171 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Calm 15mg capsule of M/s Wilshire laboratories
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator II: • Evidence of approval of required manufacturing facility "Capsule (Psychotropic)" from CLB shall be submitted.	
	Decision: Registration Board rejected the application since firm does not have approval for required manufacturing facility / section i.e., "Capsule (Psychotropic) section" from CLB.	
1253.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Metanium 30mg Capsule
	Composition	Each Capsule Contains: Temazepam……30mg
	Diary No. Date of R& I & fee	Dy.No 14170 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Calm 30mg capsule of M/s Wilshire laboratories
	GMP status	GMP inspection dated 10-8-2022, concluding good level of compliance.
	Remarks of the Evaluator [II]: • Evidence of approval of required manufacturing facility "Capsule (Psychoptropic)" from CLB shall be submitted.	
	Decision: Registration Board rejected the application since firm does not have approval for required manufacturing facility / section i.e., "Capsule (Psychotropic) section" from CLB.	
1254.	**Name and address of manufacturer / Applicant**	**M/s MBL Pharma. B-77-A, H.I.T.E, Hub, Pakistan**
	Brand Name + Dosage Form + Strength	Claricum 125mg/5ml Dry Suspension
	Composition	Each 5ml Contains: Clarithromycin…125mg
	Diary No. Date of R& I & fee	Dy.No 14166 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Biaxin 125mg/5ml by M/s Abbvie, USFDA
	Me-too status (with strength and dosage form)	Klarim Dry Suspension of M/s Amrose Pharmaceuticals, Karachi (Reg.#058105)
	GMP status	Last inspection report conducted on 31-5-2022 recommends renewal of DML.
	Remarks of the Evaluator [II]:	
	Decision: Approved. Firm shall submit source of pellets along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets before issuance of registration letter.	
1255.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Fexofan-D Tablets
	Composition	"Each Tablet Contains: Fexofenadine as HCl ……. 60mg Pseudoephedrine as HCl …..…120mg"
	Diary No. Date of R& I & fee	Dy.No 16235 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-Histamine & Sympathomimetic agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TELFAST Decongestant of Sanofi Aventis (Approved in TGA Australia)
	Me-too status (with strength and dosage form)	Fexet-D 60Mg/120Mg Tablets of Getz Pharma (Pvt.) Ltd, Karachi (Reg # 039099)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring the label claim for Fexofenadine HCl & Pseudoephedrine HCl in terms of complete salt form as well as dosage form as "Film coated bi-layer tablet" along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	

	• Submit evidence of availability of "Bi-layer compression machine."	
	Decision: Defered for evidence of availability of "Bilayer tablet compression" machine.	
1256.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	J-Uric 80mg Tablets
	Composition	Each Tablet Contains: Febuxostat……80mg
	Diary No. Date of R& I & fee	Dy.No 16233 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-Gout
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Febuxin by M/s AGP, Karachi (Reg. No. 081105)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring the dosage form as "Film coated tablet" along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim for film coated tablet along with fee of Rs. 7,500/- vide deposit slip# 737736941	
	Decision: Approved with Innovator's specifications.	
1257.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Jazolid 600mg Tablet
	Composition	Each Tablet Contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy.No 16240 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Linzol tablet 600mg of M/s Regal Pharmaceuticals
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring dosage form as "Film coated tablet" along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim for film coated tablet along with fee of Rs. 7,500/- vide deposit slip# 2007981365	
	Decision: Approved with Innovator's specifications.	
1258.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	J-Meb Plus Sachet

	Composition	Each Sachet Contains: Mebeverine HCl……135mg Psyllium Husk…….3.5gm
	Diary No. Date of R& I & fee	Dy. No 16567 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antispasmodic & laxative
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mepasm Plus Sachet of M/s Martin Dow Ltd. Karachi (Reg.# 076640)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1259.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Masqunil -Plus Capsule
	Composition	"Each Capsule Contains: Dihydroartimisinin…40mg Piperaquine Phosphate…320mg"
	Diary No. Date of R& I & fee	Dy.No 16212 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antimalarials
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dihydroartemisinin/Piperaquine (phosphate) 40mg / 320mg film-coated tablets WHO approved formulation
	Me-too status (with strength and dosage form)	Peproxin Tablets 40mg /320mg by M/s Wnsfield Pharmaceuticals (Reg#084229)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: Evidence of approval of applied formulation in capsule form. in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Firm has submitted revised composition as follows along with fee of Rs. 30,000/- vide deposit slip# 70523241 "Each film coated tablet Contains: Dihydroartimisinin…40mg Piperaquine Phosphate…320mg"	
	Decision: Approved with innovator's specifications as per following label claim: **"Each film coated tablet Contains:** **Dihydroartimisinin……40mg** **Piperaquine Phosphate……320mg"**	
1260.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Jamsolin 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulocin HCl……..0.4mg
	Diary No. Date of R& I & fee	Dy.No 16213 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Alpha 1 adrenergic receptor blocker
	Type of Form	Form 5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Uripro 0.4mg Capsule M/s Getz Pharma (Reg.#081040)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: • Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva.	
	Decision: Approved. Firm shall submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva before issuance of registration letter.	
1261	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	J-Zome 40mg Capsule
	Composition	"Each Capsule Contains: Esomeprazole…….40mg"
	Diary No. Date of R& I & fee	Dy.No 16210 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Nexium Capsules by Getz Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: • Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva. • Submit revised label claim as per innovator product declaring the salt form of Esomeprazole, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim as under along with submission of fee of Rs. 7,500/- vide deposit slip# 3667764754 "Each delayed release capsule contains: Esomeprazole as magnesium …… 40mg (in form of enteric coated pellets) • Firm has submitted source of pellets as Vision pharma	
	Decision: Approved s per following label claim: **"Each delayed release capsule contains:** **Esomeprazole as magnesium …… 40mg** **(in form of enteric coated pellets)"**	
1262	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	J-Rexin 20mg Tablets
	Composition	"Each Tablet Contains: Piroxicam As Betacyclodextrin…….20mg"
	Diary No. Date of R& I & fee	Dy.No 16237 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CYCLADOL 20 mg scored tablet. ANSM approved
	Me-too status (with strength and dosage form)	Utrahit-beta Tablet. Reg. No. 81355
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1263.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	J-Zole Sachet
	Composition	Each Sachet Contains: Omeprazole…….40mg Sodium Bicarbonate…….1680mg
	Diary No. Date of R& I & fee	Dy.No 16216 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Proton pump inhibitor/Antacid
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Risek Insta Sachet by Getz Pharma (Pvt.) Ltd., Karachi
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator II:	
	Decision: aPPROVED.	
1264.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Masqunil -Plus Sachet
	Composition	"Each Sachet Contains: Dihydroartemisinin…15mg Piperaquine Phosphate…120mg"
	Diary No. Date of R& I & fee	Dy.No 16214 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Timequin Sachet 15/120 by M/s Sami Pharmaceuticals (Pvt) Ltd, Reg No. 70787
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator II: Evidence of approval of applied formulation/drug in reference regulatory authorities adopted by Registration Board in 275th meeting or WHO approval status.	
	Decision: Deferred for evidence of approval of applied formulation/drug in reference regulatory authorities adopted by Registration Board in 275th meeting or WHO approval status.	
1265.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**

	Brand Name + Dosage Form + Strength	J-Zole 40mg Capsule
	Composition	Each Capsule Contains: Omeprazole…40mg
	Diary No. Date of R& I & fee	Dy.No 16211 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Risek Capsules by Getz Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: • Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva. • Submit revised label claim as per innovator product declaring the physical form of omepraozle, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Frim has submitted revised label claim declaring Omeprazole as enteric coated pellets along with source of pellets from M/s Vison Pharma and fee of Rs 7500/-.	
	Decision: Decision: Approved s per following label claim: **"Each delayed release capsule contains:** **Omeprazole …… 40mg** **(in form of enteric coated pellets)"**	
1266.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Malam Plus Tablets
	Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
	Diary No. Date of R& I & fee	Dy.No 16231 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status (with strength and dosage form)	Artem -DS Plus Tablets 80/480 of M/s Hilton Pharma, Karachi (Reg.# 066843)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1267.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	J-Uric 40mg Tablets
	Composition	Each Tablet Contains: Febuxostat……40mg
	Diary No. Date of R& I & fee	Dy.No 16232 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-Gout

	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Febuxin by M/s AGP, Karachi
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: • Submit revised label claim as per innovator product declaring dosage form as "Film coated tablet" along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Firm has submitted revised label claim for film coated tablet along with fee of Rs. 7,500/- vide deposit slip# 5920649868	
	Decision: Approved as per following label claim: **Each film coated tablet contains:** **Febuxostat…..…40mg**	
1268.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Deweal Plus Sachet
	Composition	"Each Sachet Contains: Ascorbic Acid…100mg Nicotinamide…50mg Riboflavin…15mg Thiamine Hcl…15mg Pyridoxine…10mg Calcium…134.64mg"
	Diary No. Date of R& I & fee	Dy.No 16217 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Multi Vitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1269.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Jenafin 125mg Tablet
	Composition	Each Tablet Contains: Terbinafine As HCl ……. 125mg
	Diary No. Date of R& I & fee	Dy.No 16228 dated 07-03-2019 Rs.20,000/- dated 07-03-2019

	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mycoderm 125mg Tablet by M/s Nabiqasim Karachi. (Reg.# 081045)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1270.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Jenafin 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine As HCl …..… 250mg
	Diary No. Date of R& I & fee	Dy.No 16229 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mycoderm Tablet by M/s Nabiqasim Karachi.
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1271.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Jeslo 5mg Tablet
	Composition	Each Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy.No 16230 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Desdine 5mg Tablet of M/s M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080821)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1272.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	J-Fylin 400mg Tablet
	Composition	Each Tablet Contains: Doxofylline…400mg

	Diary No. Date of R& I & fee	Dy.No 16238 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Xanthines
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DOXOFILLINA ABC 400mg tablet. AIFA approved
	Me-too status (with strength and dosage form)	Profylline Tablet 400mg. Reg. No. 73744
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1273.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Jazolid 400mg Tablet
	Composition	Each Tablet Contains: Linezolid…….400mg
	Diary No. Date of R& I & fee	Dy.No 16239 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Other antibacterials
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX® (linezolid) tablets (film-coated) for oral use by Pharmacia and Upjohn. not discontinued or withdrawn by USFDA for safety or efficacy reasons
	Me-too status (with strength and dosage form)	Enliv 400mg Tablet by PharmEvo (Pvt.) Ltd. Reg No. 58096
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]: Firm has submitted revised label claim for film coated tablet along with fee of Rs. 7,500/- vide deposit slip# 199132626967	
	Decision: Approved with innovator's specifications as per following label claim: **Each film coated tablet contains:** **Linezolid…….400mg**	
1274.	**Name and address of manufacturer / Applicant**	**M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan**
	Brand Name + Dosage Form + Strength	Jantial 10mg Tablet
	Composition	Each Tablet Contains: Loratadine…10mg
	Diary No. Date of R& I & fee	Dy.No 16234 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clarityn Allergy 10mg Tablets by M/s UCB Pharma, (MHRA Approved).
	Me-too status (with strength and dosage form)	Softin 10 mg Tablet by M/s Werrick Pharmaceuticals, (Reg # 012026)
	GMP status	GMP certificate issued on basis of inspection conducted on 17-06-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	

1275.	**Name and address of manufacturer / Applicant**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Brand Name + Dosage Form + Strength	Lozep 1mg Tablet
	Composition	Each Tablet Contains: Lormetazepam……1mg
	Diary No. Date of R& I & fee	Dy. No 13938 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Hypnotics and sedatives
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Lyzapam 1 mg Tablet by M/s Atco Laboratories, (Reg # 029875)
	GMP status	Last inspection was conducted on 12-02-2020 and report concludes that based on the area inspected. The people met and the document reviewed and considering the findings of the inspection firm was considered to be operating at a good level of compliance with cGMP guideline as of today.
	Remarks of the Evaluator II:	
	Decision: Deferred for evidence of approval of required manufacturing facility of "Tablet Psychotropic" section" from CLB.	
1276.	**Name and address of manufacturer / Applicant**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Brand Name + Dosage Form + Strength	Galmin 4mg/ml Oral Solution
	Composition	"Each ml Contains: Galantamine Hydrobromide Eq. To Galantamine…4mg"
	Diary No. Date of R& I & fee	Dy.No 13937 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Dy.No 13729 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Reminyl oral solution, MHRA Approved
	Me-too status (with strength and dosage form)	Dementio oral solution by M/s Reko, (Reg # 069433)
	GMP status	Last inspection was conducted on 12-02-2020 and report concludes that based on the area inspected. The people met and the document reviewed and considering the findings of the inspection firm was considered to be operating at a good level of compliance with cGMP guideline as of today.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1277.	**Name and address of manufacturer / Applicant**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Brand Name + Dosage Form + Strength	Verlin 0.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Varenicline Tartrate Eq. To Varenicline…0.5mg
	Diary No. Date of R& I & fee	Dy.No 13729 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Other nervous system drugs
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Clivin 0.5mg tablet by M/s Wilshire, (Reg # 103625)
	GMP status	Last inspection was conducted on 12-02-2020 and report concludes that based on the area inspected. The people met and the document reviewed and considering the findings of the inspection firm was considered to be operating at a good level of compliance with cGMP guideline as of today.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1278.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Ovipreg 50mg Tablet
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Diary No. Date of R& I & fee	Dy.No 16344 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gynofen 50mg Tablet. Reg No. 53337
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator [II]:	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. **Firm shall submit latest GMP inspection report conducted within last three years, before issuance of registration letter.**	
1279.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	C Praz Capsule 20mg
	Composition	Each Capsule Contains Omeprazole as enteric Coated Pellets …20mg
	Diary No. Date of R& I & fee	Dy.No 16312 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Risek Capsules by Getz Pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Source of pellets is from M/s Vision pharmaceuticals.

		Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1280.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Candasia 500mg Tablet
	Composition	Each vaginal tablet Contains: Clotrimazole…….500mg
	Diary No. Date of R& I & fee	Dy.No 16348 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specifications	BP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Gynotec 500mg Tablet of M/s. Noa Haemis Pharmaceuticals, Karachi (Reg.no. 032208)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1281.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Irbest 300mg Tablet
	Composition	"Each Film Coated Tablet Contains: Irbesartan ……. 300mg"
	Diary No. Date of R& I & fee	Dy.No 16350 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Angiotensi II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Arbi 300mg Tablet of M/s Pharmevo Karachi (Reg.# 073770)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1282.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Irbest 75mg Tablet

	Composition	Each Film Coated Tablet Contains: Irbesartan ……75mg
	Diary No. Date of R& I & fee	Dy.No 16352 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Angiotensi II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Irecon Tablet of M/s Barret (Reg.# 039725)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1283.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Cubiprofen 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…300mg
	Diary No. Date of R& I & fee	Dy.No 16351 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 300 mg film-coated tablets MHRA Approved
	Me-too status (with strength and dosage form)	Tercica 300mg Tablet. Reg. No. 58445
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1284.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Duxet Capsule 30mg
	Composition	"Each Capsule Contains: Duloxetine as HCl (Enteric Coated Pellets)…30mg"
	Diary No. Date of R& I & fee	Dy.No 16310 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dulan capsules of M/s Hilton Pharma (Pvt.) Limited Karachi (Reg.# 055447)

	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II: Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva. Firm has submitted documents for source of pellets form M/s Vision pharmaceuticals.	
	Decision: Approved.	
1285.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Duxet Capsule 60mg
	Composition	"Each Capsule Contains: Duloxetine as HCl (Enteric Coated Pellets)…60mg"
	Diary No. Date of R& I & fee	Dy.No 16309 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dulan capsules of M/s Hilton Pharma (Pvt.) Limited Karachi
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II: Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva.	
	Decision: Approved.	
1286.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Bambudil 10mg Tablet
	Composition	Each Tablet Contains: Bambuterol HCl……10mg
	Diary No. Date of R& I & fee	Dy.No 16308 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Long acting beta adreno receptor agonist
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Bambuzaf tablet of M/s Zafa Pharma 067573
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.	

1287.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Irbest 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan …150mg
	Diary No. Date of R& I & fee	Dy.No 16353 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Angiotensin II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Irecon Tablet of M/s Barret (Reg.# 039726)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1288.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Cubiprofen 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Dexibuprofen…400mg
	Diary No. Date of R& I & fee	Dy.No 16346 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Tercica 400mg Tablet of M/s Sami. Reg. No. 58446
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1289.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	C Praz Capsule 40mg
	Composition	Each Capsule Contains Omeprazole as Enteric Coated Pellets ……. 40mg
	Diary No. Date of R& I & fee	Dy.No 16311 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Risek Capsules by Getz Pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II: Firm has submitted documents for source of pellets form M/s Vision pharmaceuticals.	
	Decision: Approved.	
1290.	**Name and address of manufacturer / Applicant**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Brand Name + Dosage Form + Strength	Candasia 100mg Tablet
	Composition	Each vaginal Tablet Contains: Clotrimazole…….100mg
	Diary No. Date of R& I & fee	Dy.No 16349 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specifications	BP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Gynotec 500mg Tablet of M/s. Noa Haemis Pharmaceuticals, Karachi (Reg.no. 032207)
	GMP status	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. Capacity assessment inspection of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1291.	**Name and address of manufacturer / Applicant**	**M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Brand Name + Dosage Form + Strength	Hydrocal 1% Cream
	Composition	Each Gm Cream Contains: Hydrocortisone Acetate…1%
	Diary No. Date of R& I & fee	Dy.No 16420 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Hyzol cream of M/s Danas Pharmaceuticals (Reg.no. 041039)
	GMP status	--
	Remarks of the Evaluator II: Latest GMP inspection report conducted within last three years shall be submitted.	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1292.	**Name and address of manufacturer / Applicant**	**M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Brand Name + Dosage Form + Strength	Fusical-H Cream

	Composition	"Each Gm Cream Contains: Fusidic Acid…2% Hydrocortisone Acetate…..…1%"
	Diary No. Date of R& I & fee	Dy.No 16419 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic/Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fucidin H cream of M/s LEO Laboratories Limited, approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mirazym Cream of M/s Hiranis Karachi (Reg.# 076516)
	GMP status	--
	Remarks of the Evaluator [II]: Latest GMP inspection report conducted within last three years shall be submitted.	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter. before issuance of registration letter.	
1293.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Glovumet 50/500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 15161 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Galmet 50mg/500mg Table M/s Vision Pharma (Ref# 081905)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.	
1294.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Glovumet 50/1000mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…….50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy.No 15163 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Galmet 50mg/1000mg Table M/s Vision Pharma (Ref# 081907)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.	
1295.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Glovumet 50/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy.No 15162 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Galmet 50mg/850mg Table M/s Vision Pharma (Ref# 081906)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]: Latest GMP inspection report conducted within last three years shall be submitted.	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.	
1296.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Betanil 24mg
	Composition	"Each Tablet Contains: Betahistine Dihydrochloride……..24mg"
	Diary No. Date of R& I & fee	Dy. No 15154 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-vertigo preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Serc 24 mg tablet (Reg.# 059823)
	GMP status	GMP certificate issued on basis of inspection conducted on 3-10-2017.
	Remarks of the Evaluator [II]: Submit reference for drug product specifications. Firm has submitted revised specifications as BP, without submission of fee.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-	

	B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1297.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Zolesta 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Zolpidem Tartrate…….10mg
	Diary No. Date of R& I & fee	Dy. No 15153 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Hypnotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Olida 10mg Tablets of M/s Glitz Pharmaceuticals, Islamabad (Reg.# 081418)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]: Submit reference for drug product specifications. Firm has submitted revised specifications as USP, without submission of fee.	
	Decision: Registration Board rejected the application since firm does not have approval for required manufacturing facility of "Psychotropic Tablet section".	
1298.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Glunor 1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin HCl…….1000mg
	Diary No. Date of R& I & fee	Dy. No 15158 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Glucophage tablet of M/s Martin Dow. Ltd.
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]: Submit reference for drug product specifications. Firm has submitted revised specifications as USP, without submission of fee.	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.	
1299.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Nepzil 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Donepezil HCl…….10mg
	Diary No. Date of R& I & fee	Dy.No 15151 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Cholinesterase inhibitors
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Remembrin Tablets 10mg of M/s PharmEvo, Karachi (Reg.# 045402)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]:	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1300.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Nepzil 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Donepezil HCl…….5mg
	Diary No. Date of R& I & fee	Dy.No 15150 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Cholinesterase inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Remembrin Tablets of M/s PharmEvo, Karachi
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]:	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1301.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Betanil 16mg
	Composition	"Each Tablet Contains: Betahistine Dihydrochloride……16mg"
	Diary No. Date of R& I & fee	Dy.No 15149 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-vertigo preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Serc 16mg tablet of M/s Abbott
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]: Submit reference for drug product specifications. Firm has submitted revised specifications as BP, without submission of fee.	
	Decision: Approved with BP specification and change of brand name. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1302.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**

	Brand Name + Dosage Form + Strength	Betanil 8mg
	Composition	"Each Tablet Contains: Betahistine Dihydrochloride……8mg"
	Diary No. Date of R& I & fee	Dy.No 15148 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-vertigo preparations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Serc 8mg tablet of M/s Abbott
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator II: Submit reference for drug product specifications. Firm has submitted revised specifications as BP, without submission of fee.	
	Decision: Approved with BP specification and change of brand name. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1303.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Glunor 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin HCl……500mg
	Diary No. Date of R& I & fee	Dy.No 15156 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Glucophage tablet of M/s Martin Dow. Ltd.
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator II: Submit reference for drug product specifications. Firm has submitted revised specifications as USP, without submission of fee.	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1304.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Glunor 850mg Tablet
	Composition	Each Film Coated Tablet Contains: Metformin HCl……850mg
	Diary No. Date of R& I & fee	Dy.No 15157 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Glucophage tablet of M/s Martin Dow. Ltd.
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator II: Submit reference for drug product specifications. Firm has submitted revised specifications as USP, without submission of fee.	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1305.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Danfol Tablet 5mg
	Composition	Each Tablet Contains: Folic Acid……5mg
	Diary No. Date of R& I & fee	Dy.No 15155 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin B9
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Zal 5mg tablet of M/s Alson Pharmaceuticals (Reg.#038180)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator II:	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1306.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Alziment 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Memantine as HCl…….10mg
	Diary No. Date of R& I & fee	Dy.No 15152 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Psychoanaleptics.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dmantin 10mg Tablets by M/s Genome Pharmaceuticals (Reg.#056078)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator II:	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1307.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**

	Brand Name + Dosage Form + Strength	Gabfast Capsule 25mg
	Composition	Each Capsule Contains: Pregabalin…….25mg
	Diary No. Date of R& I & fee	Dy.No 15164 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Neugalin 25mg capsule of M/s Barret Hodgson (Reg.#086001)
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator II: BP monograph is available for applied formulation.	
	Decision: Approved with BP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1308.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Istamet Tablet 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 15159 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifcations
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sitamet Tablets by M/s CCL Pharmaceuticals
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specification. The firm shall submit revised label claim as per innovator product for salt form of Sitagliptin with master formulation and fee of Rs. 30,000/- for correction/pre-approval change in product specifications and composition, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1309.	**Name and address of manufacturer / Applicant**	**M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Istamet Tablet 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy.No 15160 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifcations
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sitamet Tablets by M/s CCL Pharmaceuticals
	GMP status	GMP certificate issued on basis of inspection conducted on 03-10-2017.
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specification. The firm shall submit revised label claim as per innovator product for salt form of Sitagliptin with master formulation and fee of Rs. 30,000/- for correction/pre-approval change in product specifications and composition, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter.	
1310.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Fencare 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Aceclofenac…….100mg
	Diary No. Date of R& I & fee	Dy.No 14768 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Rheumatoid arthritis
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Aclofen Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg.# 068419)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specification. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1311.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Nimcare 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Nimesulide…100mg
	Diary No. Date of R& I & fee	Dy.No 14767 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAIDS
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ALGIMESIL 100 mg tablets AIFA Italy Approved
	Me-too status (with strength and dosage form)	Nimcid Tablets by Unexolabs (Reg#46336)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator [II]: Submit revised label claim as per innovator product declaring dosage form as uncoated tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved with Innovator's specifications as per following label claim: **"Each Tablet Contains:** **Nimesulide ……. 100mg"**	

	• **Firm shall submit revised master formulation declaring dosage form as uncoated tablet along fee of Rs. 7,500/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.**	
1312.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Diclovetor SR 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Diclofenac Sodium…100mg"
	Diary No. Date of R& I & fee	Dy.No 14770 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antirheumatics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRo
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Medifenac SR 100mg Tablet of M/s M/s. Mediate Pharmaceuticals, Karachi (Reg.# 048703)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring dosage form as film coated sustained release tablet along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved as per following label claim: **"Each Film Coated sustained release Tablet Contains:** **Diclofenac Sodium …….100mg"** • **Firm shall submit revised master formulation declaring dosage form as film coated sustained release tablet along fee of Rs. 30,000/-/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.**	
1313.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Inospon 80/80 mg Tablet
	Composition	Each Sugar Coated Tablet Contains: Phloroglucinol……80mg Trimethylphloroglucinol……80mg
	Diary No. Date of R& I & fee	Dy.No 14769 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SPASFON (ANSM approved)
	Me-too status (with strength and dosage form)	Spasrid tablets of M/s Barret Hodgson (Reg.# 034743)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring hydrated salt form of phloroglucinol along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved with innovator's specifications. Firm shall submit revised label claim as per innovator product declaring hydrated salt form of phloroglucinol along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
1314.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**

	Brand Name + Dosage Form + Strength	Infast 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac Potassium…75mg
	Diary No. Date of R& I & fee	Dy.No 14771 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Beflam 75mg Tablet by M/s BatalaPharmaceuticals Reg.#031128
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator II: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: In order to dispose of new applications of Diclofenac Potassium 75mg tablet, the Board requested Pharmacy Services Divison to intimate PE&R Division regarding provision of safety and efficacy studies approved bv any credible sources and shared by manufcaturers and if no such studies are available than PMA will conduct safety and efficacy trials as per Bio study rules, 2017, as decided by Appellate Board in 162nd meeting.	
1315.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Devotor 2.5mg/5ml Syrup
	Composition	Each 5ml Contains: Desloratadine ……. 2.5mg
	Diary No. Date of R& I & fee	Dy.No 14766 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aerius For Children Syrup Desloratadine 2.5mg/5mL oral liquid bottle by M/s Bayer Australia Ltd (TGA approved)
	Me-too status (with strength and dosage form)	Desora 0.5mg/ml syrup by M/s Continental Pharma. (Reg.# 055192)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1316.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Cefo 40mg/5ml Oral Suspension
	Composition	Each 5ml Contains: Cefpodoxime Proxetil Eq. To Cefpodoxime…40mg
	Diary No. Date of R& I & fee	Dy.No 14766 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Third generation Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefpodoxime 40mg/5ml granules for oral suspension by Milpharm Limited (MHRA)

	Me-too status (with strength and dosage form)	Xipodox 40mg /5ml by M/s. Vega Pharmaceuticals, Lahore
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator [II]:	
	Decision: Decision: Approved.	
1317.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Ferrax 100/0.35 mg Tablet
	Composition	Each Film Coated Tablet Contains: Iron Polymaltose…….100mg Folic Acid…….0.35mg
	Diary No. Date of R& I & fee	Dy.No 14766 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-anaemic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Ipomalt -F Tablets of M/s Rock Pharmaceutical Laboratories (Pvt) Ltd. (Reg.# 077301)
	GMP status	--
	Remarks of the Evaluator [II]: Submit revised label claim the complete salt form of iron polymaltose and declare strength in term of the elemental Iron, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved with Innovator's specifications, as per following label claim: **"Each Film Coated Tablet Contains:** **Iron (III) Hydroxide Polymaltose complex eq. to elemental Iron …….... 100mg** **Folic Acid ……. 0.35mg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product composition as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.**	
1318.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Instron 8mg/4ml Injection
	Composition	Each 4ml Contains: Ondansetron as HCl Dihydrate ……..… 8mg
	Diary No. Date of R& I & fee	Dy.No 14764 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-emetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Onset Injection of M/s Pharmedic
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator [II]: Submit reference for drug product specifications.	

	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1319.	**Name and address of manufacturer / Applicant**	**M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Amlotin 5/20 mg Tablet
	Composition	Each Tablet Contains: Amlodipine As Besylate…5mg Atorvastatin As Calcium……20mg
	Diary No. Date of R& I & fee	Dy.No 14772 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Caduet 5mg/20mg Tablet by M/s Pfizer Laboratories ltd., Karachi (Reg.#041198)
	GMP status	GMP inspection conducted on 13-09-2022 concluded good GMP compliance.
	Remarks of the Evaluator [II]: Submit revised label claim as per innovator product declaring the hydrate form of Atorvastatin calcium and dosage form as film coated tablet, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved with USP specifications as per following label claim: **"Each film coated tablet contains:** **Amlodipine as besylate …… 5mg** **Atorvastatin as calcium trihydrate …… 20mg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product composition as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1320.	**Name and address of manufacturer / Applicant**	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate, Raiwind, Lahore**
	Brand Name + Dosage Form + Strength	Lepsi 750mg XR Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Levetiracetam……..750mg
	Diary No. Date of R& I & fee	Dy.No 32419 dated 28-09-2018 Rs.50,000/- dated 28-09-2018
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Lerace XR 750mg tablet of M/s Hilton Pharma (Reg.#107780)
	GMP status	--
	Remarks of the Evaluator [II]: USP monograph is available for applied formulation whereas firm has applied in-house specifications. Submit revised drug product specifications as per USP along with fee of Rs. 7,500/- for pre-approval change/correction in drug product specifications as per as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. **Firm's response:** Firm has submitted fee of Rs. 7,500/- vide deposit slip# 764518731377 for change of drug product specifications to USP.	
	Decision: Approved with USP specifications.	
1321.	**Name and address of manufacturer / Applicant**	**M/s Novex Pharmaceuticals. Plot # 54,S6, National Industrial Zone RCCI, Rawat, Islamabad**

	Brand Name + Dosage Form + Strength	Pironox 20mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Piroxicam…20mg
	Diary No. Date of R& I & fee	Dy. No 14876 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSMA of France
	Me-too status (with strength and dosage form)	Rheupain injection of M/s Mediate Pharma (Reg.#061926)
	GMP status	GMP inspection conducted on 12-020-2019 recommends grant of DML.
	Remarks of the Evaluator II: Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.	
1322.	**Name and address of manufacturer / Applicant**	**M/s Novex Pharmaceuticals. Plot # 54,S6, National Industrial Zone RCCI, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Water for Injection 5ml
	Composition	"Each Ampoule Contains: Water For Injection….. 5ml"
	Diary No. Date of R& I & fee	Dy.No 14887 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Diluent
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Water for injection of Martin Dow
	GMP status	GMP inspection conducted on 12-020-2019 recommends grant of DML.
	Remarks of the Evaluator II: Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1323.	**Name and address of manufacturer / Applicant**	**M/s Novex Pharmaceuticals. Plot # 54,S6, National Industrial Zone RCCI, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Cynox 1000mcg/ml Injection
	Composition	Each ml Ampoule Contains: Cynacobalamin…….1000mcg
	Diary No. Date of R& I & fee	Dy.No 14890 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Cyfort Injection M/s Swiss Pharma
	GMP status	GMP inspection conducted on 12-020-2019 recommends grant of DML.

	Remarks of the Evaluator II: Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1324.	**Name and address of manufacturer / Applicant**	**M/s Novex Pharmaceuticals. Plot # 54,S6, National Industrial Zone RCCI, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Cynox plus Injection
	Composition	Each 3ml Ampoule Contains: Vitamin B1…100mg Vitamin B6…100mg Vitamin B12…1000mcg
	Diary No. Date of R& I & fee	Dy.No 14888 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer' sspecifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Neurobion solution for Injection 3ml by M/s Merck Selbstmedikation GmbH (Germany Approved)
	Me-too status (with strength and dosage form)	Neurolina Injection 3ml by M/s Alina Combine (Reg#076143)
	GMP status	GMP inspection conducted on 12-02-2019 recommends grant of DML.
	Remarks of the Evaluator II: Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1325.	**Name and address of manufacturer / Applicant**	**M/s Novex Pharmaceuticals. Plot # 54,S6, National Industrial Zone RCCI, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Nospasm 20mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Hyoscine N-Butylbromide.....20mg
	Diary No. Date of R& I & fee	Dy.No 14884 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticholinergic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer' specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Buscopan injection approved by Bfarm of Germany.
	Me-too status (with strength and dosage form)	Buscocin Injection by M/s Caraway Pharmaceuticals (Reg#069927)
	GMP status	GMP inspection conducted on 12-02-2019 recommends grant of DML.
	Remarks of the Evaluator II: Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years, before issuance of registration letter before issuance of registration letter.	
1326.	**Name and address of manufacturer / Applicant**	**M/s Novex Pharmaceuticals. Plot # 54,S6, National Industrial Zone RCCI, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Artim 80mg/ml Injection
	Composition	Each ml Ampoule Contains: Artemether…80mg
	Diary No. Date of R& I & fee	Dy.No 14895 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	IP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO approved formulation
	Me-too status (with strength and dosage form)	Artesinate Injection of M/S Gray's Pharmaceuticals, Reg. No. 72458
	GMP status	GMP inspection conducted on 12-02-2019 recommends grant of DML.
	Remarks of the Evaluator [II]: Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1327.	**Name and address of manufacturer / Applicant**	**M/s Novex Pharmaceuticals. Plot # 54,S6, National Industrial Zone RCCI, Rawat, Islamabad**
	Brand Name + Dosage Form + Strength	Metoclop 10mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Metoclopramide HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 14866 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antiemetic/ Dopamine D2 Receptor Antagonists
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	METOCLOPRAMIDE 10mg/2ml Solution for Injection by M/s Advanz Pharma, MHRA Approved.
	Me-too status (with strength and dosage form)	Metanil Injection 10mg/2ml by M/s Dosaco Laboratories, Reg. No. 25510
	GMP status	GMP inspection conducted on 12-02-2019 recommends grant of DML.
	Remarks of the Evaluator [II]: Latest inspection report conducted within last three years shall be submitted.	
	Decision: Approved. Firm shall submit revised label claim as per innovator product declaring the monohydrate form of Metoclopramide hydrochloride and quantity of active ingredient in terms of the equivalent amount of anhydrous metoclopramide hydrochloride with fee of Rs. 30,000/- for correction/pre-approval change in composition as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest inspection report conducted within last three years	
1328.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Ozapyn 5mg Tablet
	Composition	Each Tablet Contains: Olanzapine …… 5mg
	Diary No. Date of R& I & fee	Dy.No 17188 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Olanzapine 5 mg Tablets. By: Akson Pharmaceuticals Pvt Ltd. Mirpur.
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved with USP specifications as per following label claim: **Each film coated tablet contains:** **Olanzapine …… 5mg.**	

	• **Firm shall submit fee of Rs. 7,500/- for correction/pre-approval change to film coated tablet as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 before issuance of registration letter.**	
1329.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Ozapyn 10mg Tablet
	Composition	Each Tablet Contains: Olanzapine…10mg
	Diary No. Date of R& I & fee	Dy.No 17193 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Olanzpine 10 mg Tablets. By: Akson Pharmaceuticals Pvt Ltd. Mirpur. (Reg.#081661)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved with USP specifications as per following label claim: **Each film coated tablet contains:** **Olanzapine …… 10mg.** • **Firm shall submit fee of Rs. 7,500/- for correction/pre-approval change to film coated tablet as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 before issuance of registration letter.**	
1330.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Kaytine 20mg Tablet
	Composition	Each Tablet Contains: Paroxetine…20mg
	Diary No. Date of R& I & fee	Dy.No 17192 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK.
	Me-too status (with strength and dosage form)	Neoxetine Tablets 20mg of M/s Neomedix Pharmaceuticals, Islamabad (Reg.# 081407)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring dosage form as film coated tablet and complete salt form of Paroxetine along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet and complete salt form of Paroxetine along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 before issuance of registration letter.	
1331.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**

	Brand Name + Dosage Form + Strength	Kesiflam 100mg SR Tablet
	Composition	Each film coated sustained release Tablet Contains: Diclofenac Sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 17196 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antirheumatics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Medifenac SR 100mg Tablet of M/s M/s. Mediate Pharmaceuticals, Karachi (Reg.# 048703)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1332.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Cipex 125mg/5ml Suspension
	Composition	Each 5ml Contains: Ciprofloxacin…125mg
	Diary No. Date of R& I & fee	Dy.No 17184 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Registration Board on the recommended dosage basis
	Me-too status (with strength and dosage form)	Quash 125mg/5ml suspension of M/s Wilshire Laboratories Pvt. Ltd.
	GMP status	
	Remarks of the Evaluator II: • Submit details for source of drug substance pellets along with, COA, GMP certificate and stability studies. Details of the accompanying diluent for reconstitution shall be submitted along with the manufacturing area in which it will be produced	
	Decision: Approved. Alongwith diluent as per innovator drug product. Firm shall submit details for source of drug substance pellets along with, COA, GMP certificate and stability studies before issuance of registration letter.	
1333.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Repdon 1mg Tablet
	Composition	Each Tablet Contains: Risperidone…1mg
	Diary No. Date of R& I & fee	Dy.No 17190 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tablet Resjun -1 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081921)

	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator II: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 before issuance of registration letter.	
1334.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Repdon 3mg Tablet
	Composition	Each Tablet Contains: Risperidone…3mg
	Diary No. Date of R& I & fee	Dy.No 17194 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Becalm 3mg Tablet of M/s Maple Pharmaceuticals, Karachi (Reg.# 058206)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator II: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 before issuance of registration letter.	
1335.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries Pvt. Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Repdon 4mg Tablet
	Composition	Each Tablet Contains: Risperidone…4mg
	Diary No. Date of R& I & fee	Dy.No 17195 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Riss 4mg Tablet of M/s M/s Shawan Pharmaceuticals, Islamabad (Reg.# 080376)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator II: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 before issuance of registration letter.	
1336.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**

	Brand Name + Dosage Form + Strength	Tadol 100mg/2ml Injection
	Composition	Each 2ml Contains: Tramadol…….100mg
	Diary No. Date of R& I & fee	Dy.No 17200 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tremomed 100mg injection by M/s Medicraft Pharmaceuticals (Pvt.) Ltd. (Reg#064484)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring salt form of drug substance along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring salt form of drug substance along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 before issuance of registration letter.	
1337.	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Cipex 250mg/5ml Suspension
	Composition	Each 5ml Contains: Ciprofloxacin……..250mg
	Diary No. Date of R& I & fee	Dy.No 17198 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Quash suspension of M/s Wilshire Laboratories Pvt. Ltd.
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020.
	Remarks of the Evaluator [II]: • Submit details for source of drug substance pellets along with, COA, GMP certificate and stability studies. Details of the accompanying diluent for reconstitution shall be submitted along with the manufacturing area in which it will be produced	
	Decision: Approved. Firm shall submit details for source of drug substance pellets along with, COA, GMP certificate and stability studies.	
1338.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Apzole Tablets 15mg
	Composition	Each Tablet Contains: Aripiprazole……15mg
	Diary No. Date of R& I & fee	Dy.No 14858 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Aripa tablet 15 mg by M/s Platinum Reg. No. 055709
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator [II]: Reference for drug product specifications shall be submitted. Firm has referred to USP specification with submission of fee of Rs. 7,500/- vide deposit slip# 7619139035.	
	Decision: Approved with USP specifications.	
1339.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Doris 200000 Chews
	Composition	Each Chewable Tablet Contains: Cholecalciferol …200000 IU
	Diary No. Date of R& I & fee	Dy.No 14861 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Vitamin D
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.	
	Decision: Deferred fro following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.**	
1340.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Apzole Tablets 20mg
	Composition	Each Tablet Contains: Aripiprazole……20mg
	Diary No. Date of R& I & fee	Dy.No 14859 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Aripaze tablet 20 mg by M/s Global Reg. No. 054729
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator [II]: Reference for drug product specifications shall be submitted.	

	Firm has referred to USP specification with submission of fee of Rs. 7,500/- vide deposit slip# 9640161993.	
	Decision: Approved with USP specifications.	
1341.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Apzole Tablets 30mg
	Composition	Each Tablet Contains: Aripiprazole……30mg
	Diary No. Date of R& I & fee	Dy.No 14860 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Apify 30mg Tablet by M/s Akhai Pharma (Reg#76249)
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator II: Reference for drug product specifications shall be submitted. Firm has referred to USP specification with submission of fee of Rs. 7,500/- vide deposit slip# 52065006.	
	Decision: Approved with USP specifications.	
1342.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt. Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Apzole Tablets 10mg
	Composition	Each Tablet Contains: Aripiprazole……10mg
	Diary No. Date of R& I & fee	Dy.No 14857 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Aripa tablet 10 mg by M/s Platinum Reg. No. 055708
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator II: Reference for drug product specifications shall be submitted. Firm has referred to USP specification with submission of fee of Rs. 7,500/- vide deposit slip# 886684540944.	
	Decision: Approved with USP specifications.	
1343.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Zercept Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Donepezil HCl…….10mg
	Diary No. Date of R& I & fee	Dy.No 14854 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholinesterase inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Remembrin Tablets 10mg of M/s PharmEvo, Karachi (Reg.# 045402)
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator II: Reference for drug product specifications shall be submitted. Firm has referred to USP specification with submission of fee of Rs. 7,500/- vide deposit slip# 99503387.	
	Decision: Approved with USP specifications.	
1344.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Zercept Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Donepezil HCl…….5mg
	Diary No. Date of R& I & fee	Dy.No 14853 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholinesterase inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Remembrin Tablets 5mg of M/s PharmEvo, Karachi (Reg.# 045401)
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator II: Reference for drug product specifications shall be submitted. Firm has referred to USP specification with submission of fee of Rs. 7,500/- vide deposit slip# 17420483727.	
	Decision: Approved with USP specifications.	
1345.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Misotol 200mcg Tablet
	Composition	"Each Tablet Contains: Misoprostol……..200mcg"
	Diary No. Date of R& I & fee	Dy.No 14851 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tecmiso 200mcg tablet of M/s NabiQasim Karachi (Reg.# 076133)
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator II: • Reference for drug product specifications shall be submitted. • Clarification shall be submitted in label claim regarding physical form of drug substance whether it is in "dispersion form" of pure drug substance. **Firm's reply:** Please note that the specification of finished form of product is Innovator's Specification.	

	Regarding physical form of drug substance, please note that we will use the dispersion form of misoprostol (with 1% HPMC) as the pure drug substance available in liquid form which is highly unstable. Firm has submitted following revised label claim along with fee of Rs. 7,500/- vide deposit slip# 2696171561: "Misotol 200mcg Tablets Each Tablet contains; Misoprostol (as 1% HPMC) …….200mcg" • IP monograph is available for applied formulation.	
	Decision: Approved with IP specifications as per following label claim: **"Misotol 200mcg Tablets** **Each Tablet contains;** **Misoprostol (as 1% HPMC) …….200mcg"** **Firm shall submit deifferential fee of Rs. 22,500/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1346.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Misotol 100mcg Tablet
	Composition	"Each Tablet Contains: Misoprostol……..100mcg"
	Diary No. Date of R& I & fee	Dy.No 14850 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Tecmiso 100mcg tablet of M/s NabiQasim Karachi (Reg.# 076132)
	GMP status	GMP certificate was issued based on inspection conducted on 29 October 2020.
	Remarks of the Evaluator [II]: • Reference for drug product specifications shall be submitted. • Clarification shall be submitted in label claim regarding physical form of drug substance whether it is in "dispersion form" of pure drug substance. **Firm's reply:** Please note that the specification of finished form of product is Innovator's Specification. Regarding physical form of drug substance, please note that we will use the dispersion form of misoprostol (with 1% HPMC) as the pure drug substance available in liquid form which is highly unstable. Firm has submitted following revised label claim along with fee of Rs. 7,500/- vide deposit slip# 724835384: Misotol 100mcg Tablets Each Tablet contains; Misoprostol (as 1% HPMC) ……. 100mcg" • IP monograph is available for applied formulation.	
	Decision: Approved with IP specifications as per following label claim: **"Misotol 100mcg Tablets** **Each Tablet contains;** **Misoprostol (as 1% HPMC) ……. 100mcg"** **Firm shall submit deifferential fee of Rs. 22,500/- for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1347.	**Name and address of manufacturer / Applicant**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Brand Name + Dosage Form + Strength	Angiclor Tablet 90mg

	Composition	Each Film Coated Tablet Contains: Ticagrelor…….90mg
	Diary No. Date of R& I & fee	Dy.No 14862 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anticoagulant/ antiplatelet agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Virata tablet of M/s Sami Pharma
	GMP status	GMP certificate was issued based on inspection conducted on 29th October 2020.
	Remarks of the Evaluator II: • Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. **Frim's reply:** We have submitted 06 months stability data (Accelerated & Real Time) of said product on 19th July,2022.	
	Decision: Deferred for evaluation of submitted stability studies data on its turn.	
1348.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Misodic 75mg/200mcg Tablet
	Composition	Each Tablet Contains: Diclofenac Sodium……75mg Misoprostol……200mcg
	Diary No. Date of R& I & fee	Dy.No 15948 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Prostaglandin E1 Analogue, NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Arthrotec of USFDA Approved
	Me-too status (with strength and dosage form)	Cytopan-75 Tablets by Getz Pharma (Reg#024014)
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator II: • Submit revised label claim as per innovator product declaring the misoprostol layer as immediate release and diclofenac sodium layer as enteric coated along with submission of relevant fee as per. Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. • Submit evidence of availability of bilayer compression machine.	
	Decision: Deferred for evidence of availability of "Bi-layer compression" machine along with its IQ,OQ & PQ reports.	
1349.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Pathoderm B Cream
	Composition	Each Tube Contains: Fusidic Acid…0.2% Betamethasone As Valerate…0.1%
	Diary No. Date of R& I & fee	Dy.No 15808 dated 07-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xemacort 20 mg/g + 1 mg/g cream (MHRA Approved)

	Me-too status (with strength and dosage form)	Beta-F Cream by Atco Laboratories (Reg# 082104)
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1350.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Doioraleze 2mg Capsule
	Composition	"Each Capsule Contains: Loperamide HCl……2mg"
	Diary No. Date of R& I & fee	Dy.No 15939 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Anti-propulsives
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	GASTRO-STOP loperamide hydrochloride 2mg capsules. TGA approved
	Me-too status (with strength and dosage form)	IMODIUM 2MG Capsule. Reg. No. 6159
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1351.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Flucole 150mg Capsule
	Composition	Each Capsule Contains: Fluconazole…150mg
	Diary No. Date of R& I & fee	Dy.No 15800 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azocan 150 of M/s FDC International Ltd. approved by MHRA of UK
	Me-too status (with strength and dosage form)	Fantizol Capsule by M/ Apex Karachi. (Reg#073551)
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]: Firm has applied in-house specifications whereas JP monograph is available for applied formulation.	
	Decision: Approved with JP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1352.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Davifucin 20mg Ointment
	Composition	Each Tube Contains: Sodium Fusidate…20mg/Gm
	Diary No. Date of R& I & fee	Dy.No 15856 dated 07-03-2019 Rs.20,000/- dated 05-03-2019
	Pharmacological Group	Antibiotic for topical use

	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approve by MHRA of UK
	Me-too status (with strength and dosage form)	Fusimax 2% ointment of M/s Maxitech
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]:	
	Decision: Approved with BP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1353.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Topogyne 200mcg Tablet
	Composition	"Each Tablet Contains: Misoprostol…….200mcg"
	Diary No. Date of R& I & fee	Dy.No 15879 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tecmiso 200mcg tablet of M/s NabiQasim Karachi (Reg.# 076133)
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]: • Reference for drug product specifications shall be submitted. • Clarification shall be submitted in label claim regarding physical form of drug substance whether it is in "dispersion form" of pure drug substance.	
	Decision: Approved with IP specifications as per following label claim: **"Each Tablet contains:** **Misoprostol (as 1% HPMC) ……. 200mcg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product composition as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1354.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Davisulide 100mg Tablet
	Composition	Each Tablet Contains: Nimesulide…100mg
	Diary No. Date of R& I & fee	Dy.No 15871 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (with strength and dosage form)	Nims tablet by M/s Sami

	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]: • Registration Board in its 271st meeting keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board approved the formulation of Nimesulide Tablets 100mg with a pack size for 15 days as per recommendations of EMA only for the following clinical indications as a second-line choice. a) Treatment of acute pain b) Primary dysmenorrhea	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1355.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Dermazole Cream
	Composition	Each tube Contains: Betamethasone Dipropionate Eq. To Betamethasone……0.05% Clotrimazole……1%
	Diary No. Date of R& I & fee	Dy.No 15819 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Antifungal with corticosteroids
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LOTRISONE® (clotrimazole and betamethasone dipropionate) cream, for topical use (1%/0.05%). USFDA Approved
	Me-too status (with strength and dosage form)	Holfungin Cream. Reg. No. 67598
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]:	
	Decision: Approved.	
1356.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Betasone 0.1% Cream
	Composition	"Each Gram Contains: Betamethasone As Valerate…1mg"
	Diary No. Date of R& I & fee	Dy.No 15859 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifcations
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Betamethasone (as) Valerate 0.1%w/w Cream. MHRA Approved
	Me-too status (with strength and dosage form)	Beason Cream 0.1%. Reg. No. 80082
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]: BP monograph is available for applied formulation.	
	Decision: Approved with BP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
1357.	**Name and address of manufacturer / Applicant**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Brand Name + Dosage Form + Strength	Daviscab Cream

	Composition	Each Gram Contains: Permethrin……50mg
	Diary No. Date of R& I & fee	Dy.No 15813 dated 07-03-2019 Rs.20,000/- dated 04-03-2019
	Pharmacological Group	Pyrethrines, incl. synthetic compounds
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Betamethasone (as) Valerate 0.1%w/w Cream. MHRA Approved
	Me-too status (with strength and dosage form)	Permisan 5% cream of M/s Sante Reg. No. 061887
	GMP status	GMP certificate issued on basis of inspection conducted on 02-02-2022.
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

b. Deferred cases

1358	**Name and address of manufacturer / Applicant**	**"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore** Contract manufacturing by **M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"**
	Brand Name +Dosage Form + Strength	D-Next 5mg/ml IV/IM Injection
	Composition	"Each 1ml Contains: Cholecalciferol (Vitamin D3)…5mg"
	Diary No. Date of R& I & fee	Dy. No 17650 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.

		• Reference product is available in ampoule whereas firm has applied for vial.
	Decision of 291st meeting: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore. Moreover, clarification shall be submitted regarding container closure system, since reference product is available in ampoule whereas firm has applied for vial.	
	Firm's response: Firm has referred to the Capacity assessment inspection report of M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore presented in 295th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections: • Dry Powder Injection (Cephalosporin) Section • Dry Powder Suspension (Cephalosporin) Section • Capsule (Cephalosporin) Section • General Liquid Injection (Ampoule) • General Liquid Injection Vials (SVP)	
	Decision of 320th meeting: Registration Board deferred the applications of contract manufacturing from M/s Medisave pharmaceuticals, Plot 578-579, Sunder Industrial Estate, Lahore, Pakistan for submission of upgradation plan regarding increase in testing capacity especially HPLC, microbiological testing etc to cater the need of pharmacopoeial testing of already registered drug products, products under development and contract manufactured products as decided in 317th meeting of Registration Board.	
	Remark Evaluator: Subsequent evaluation of record has revealed that decision of Board was erroneously drafted as deferred considering the drug product manufacturer as M/s Medisave, whereas firm has applied for contract manufacturing from Novamed Pharmaceuticals (Pvt) Ltd.	
	Decision: Registration Board noted the information and decided to approve the applied product of D-Next 5mg/ml IV/IM Injection with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore.**	
1359.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/5mg
	Composition	Each Tablet Contains: Telmisartan…40mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8173 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 60's: Rs.600/-, Rs.840/-, Rs.1200/-, Rs.1680/-, Rs.1800/-, Rs.3600/-, As per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion:

		The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision of 296th meeting: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
	Firm's response: Firm has submitted following: • Commercial invoice and operational manual for Rotary press machine ZPW-26 having capacity of bilayer compression. • Revised manufacturing outline for bi-layer tablet. • GMP certificate issue don basis of inspection conducted on 06-12-2021. • Reference of their already registered bi-layer product of Mobikare plus tablet 50/200 (Diclofenac/Misoprostol)	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with IQ, OQ & PQ reports for the "bilayer compression machine" before issuance of registration letter.	
1360.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/10mg
	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8172 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Me-too status	Telday Plus 80/10 Tablets of M/s. Novamed Pharmaceuticals
	Approval status of product in reference regulatory authorities	Approved in USFDA
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision of 296th meeting: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
	Firm's response: Firm has submitted following: • Commercial invoice and operational manual for Rotary press machine ZPW-26 having capacity of bilayer compression. • Revised manufacturing outline for bi-layer tablet. • GMP certificate issue don basis of inspection conducted on 06-12-2021. • Reference of their already registered bi-layer product of Mobikare plus tablet 50/200 (Diclofenac/Misoprostol)	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with IQ, OQ & PQ reports for the "bilayer compression machine" before issuance of registration letter.	
1361.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 80mg/5mg

	Composition	Each Tablet Contains: Telmisartan…80mg Amlodipine besylate eq to Amlodipine…5mg
	Diary No. Date of R&I & Fee	Dy.No 8175 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 80/5 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision of 296th meeting: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
	Firm's response: Firm has submitted following: • Commercial invoice and operational manual for Rotary press machine ZPW-26 having capacity of bilayer compression. • Revised manufacturing outline for bi-layer tablet. • GMP certificate issue don basis of inspection conducted on 06-12-2021. • Reference of their already registered bi-layer product of Mobikare plus tablet 50/200 (Diclofenac/Misoprostol)	
	Decision of 323rd meeting: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with IQ, OQ & PQ reports for the "bilayer compression machine" before issuance of registration letter.	
1362.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi
	Brand Name + Dosage Form + Strength	Telbar Plus Tablet 40mg/10mg
	Composition	Each tablet contains Telmisartan…40mg Amlodipine besylate eq to Amlodipine…10mg
	Diary No. Date of R&I & Fee	Dy.No 8174 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	: as per SRO
	Approval status of product in reference regulatory authorities	Approved in USFDA
	Me-too status	Telday Plus 40/10 Tablets of M/s. Novamed Pharmaceuticals
	GMP status	Dated: 16th-28th Aug, 2018. Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator	
	Decision of 296th meeting: Deferred for confirmation of bi-layered tablet machine and revision of manufacturing outline.	
	Firm's response: Firm has submitted following:	

	• Commercial invoice and operational manual for Rotary press machine ZPW-26 having capacity of bilayer compression. • Revised manufacturing outline for bi-layer tablet. • GMP certificate issue don basis of inspection conducted on 06-12-2021. • Reference of their already registered bi-layer product of Mobikare plus tablet 50/200 (Diclofenac/Misoprostol)	
	Decision of 323rd meeting: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with IQ, OQ & PQ reports for the "bilayer compression machine" before issuance of registration letter.	
1363.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore BY M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Brand Name +Dosage Form + Strength	SMP Insta Sachet 20/1680mg
	Composition	Each Sachet Contains: Omeprazole Sodium…20mg Sodium Bicarbonate….1680mg
	Diary No. Date of R& I & fee	Dy. No. 12427 dated 06.03.2019 Rs. 50,000/- dated 04.03.2019
	Pharmacological Group	Proton pump inhibitor and antacid
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole and sodium bicarbonate (Packet) for oral suspension. approved by US-FDA
	Me-too status	Risek Insta Sachet. Reg. No. 58547
	GMP status	GMP inspection reports required.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm did not submit the requirements /documents as per enclosure of Form 5. • The firm did not submit copy of contract manufacturing agreement. • The fee has been deposited by M/s Biomark Pharmaceuticals.
	Decision of 317th meeting: Deferred for submission of: • Requirements /documents as per enclosure of Form 5. • copy of contract manufacturing agreement. • Application Fee of Rs. 75,000/-.	
	Firm's response: Firm has submitted following: • Complete enclosures of Form 5. • Contract agreement between M/s Sapient pharma and M/s Bio Mark Pahrma • Drug product specifications as per USP • GMP certificate of Bio-mark issued on basis of inspection conducted on 13-02-2020	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore.**	
1364.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore by M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore

	Brand Name +Dosage Form + Strength	SMP Insta Sachet 40/1680mg
	Composition	Each Sachet Contains: Omeprazole Sodium…40mg Sodium Bicarbonate….1680mg
	Diary No. Date of R& I & fee	Dy. No. 12428 dated 06.03.2019 Rs. 50,000/- dated 04.03.2019
	Pharmacological Group	Proton pump inhibitor and antacid
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole and sodium bicarbonate (Packet) for oral suspension. approved by US-FDA
	Me-too status	Risek Insta Sachet. Reg. No. 58548
	GMP status	GMP inspection reports required.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • The firm did not submit the requirements /documents as per enclosure of Form 5. • The firm did not submit copy of contract manufacturing agreement. • The fee has been deposited by M/s Biomark Pharmaceuticals.
	Decision: Deferred for submission of: • requirements /documents as per enclosure of Form 5. • copy of contract manufacturing agreement. • Application Fee of Rs. 75,000/-.	
	Firm's response: Firm has submitted following: • Complete enclosures of Form 5. • Contract agreement between M/s Sapient pharma and M/s Bio Mark Pahrma • Drug product specifications as per USP • GMP certificate of Bio-mark issue don basis of inspection conducted on 13-02-2020	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore.**	
1365.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore BY M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Brand Name +Dosage Form + Strength	Sapeso Capsule 20mg
	Composition	Each Capsule Contains: Esomeprazole as Esomeprazole Magnesium (Enteric Coated Pellets)…20mg
	Diary No. Date of R& I & fee	Dy. No. 12430 dated 06.03.2019 Rs. 50,000/- dated 04.03.2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole magnesium Capsule 20mg. USFDA Approved
	Me-too status	Esorid 20mg Capsules. Reg. No. 33097
	GMP status	GMP inspection reports required.

	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm did not submit the requirements /documents as per enclosure of Form 5. • The firm did not submit copy of contract manufacturing agreement. • The fee has been deposited by M/s Biomark Pharmaceuticals. • The firm did not submit the source of pellets and all required data.
	Decision of 317th meeting: Deferred for submission of: • requirements /documents as per enclosure of Form 5. • copy of contract manufacturing agreement. • Application Fee of Rs. 75,000/-. • source of pellets, GMP certificate of the source, and CoA and stability data of three batches of the pellets conducted in zone IV-A.	
	Firm's response: Firm has submitted following: • Complete enclosures of Form 5. • Contract agreement between M/s Sapient pharma and M/s Bio Mark Pahrma • Drug product specifications as per USP • GMP certificate of Bio-mark issue don basis of inspection conducted on 13-02-2020 • Documents for source of pellets form M/s Vision pharma	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore.**	
1366.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore BY M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Brand Name +Dosage Form + Strength	Sapeso Capsule 40mg
	Composition	Each Capsule Contains: Esomeprazole as Esomeprazole Magnesium (Enteric Coated Pellets)…40mg
	Diary No. Date of R& I & fee	Dy. No. 12431 dated 06.03.2019 Rs. 50,000/- dated 04.03.2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole magnesium Capsule 40mg. USFDA approved
	Me-too status	Espra Capsule 40mg. Reg. No. 33051
	GMP status	GMP inspection reports required.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm did not submit the requirements /documents as per enclosure of Form 5. • The firm did not submit copy of contract manufacturing agreement. • The fee has been deposited by M/s Biomark Pharmaceuticals. • The firm did not submit the source of pellets and all required data.

	Decision of 317th meeting: Deferred for submission of: • requirements /documents as per enclosure of Form 5. • copy of contract manufacturing agreement. • Application Fee of Rs. 75,000/-. • Source of pellets, GMP certificate of the source, and CoA and stability data of three batches of the pellets conducted in zone IV-A.	
	Firm's response: Firm has submitted following: • Complete enclosures of Form 5. • Contract agreement between M/s Sapient pharma and M/s Bio Mark Pahrma • Drug product specifications as per USP • GMP certificate of Bio-mark issue don basis of inspection conducted on 13-02-2020 • Documents for source of pellets form M/s Vision pharma	
	Decision: Approved with USP specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore.**	
1367.	Name and address of manufacturer / Applicant	M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore BY M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	Brand Name +Dosage Form + Strength	Moseeta Sachet 3g
	Composition	Each Sachet Contains: Dioctahedral Smectite…3gm
	Diary No. Date of R& I & fee	Dy. No. 12429 dated 06.03.2019 Rs. 50,000/- dated 04.03.2019
	Pharmacological Group	Antidiarrhoeal
	Type of Form	Form 5
	Finished Product Specification	Not submitted.
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diosmectal 3g powder of Diosmectite for oral suspension, approved by Italian Medicines Agency
	Me-too status	Semetamed 3.0g Sachets. Reg. No. 61925
	GMP status	GMP inspection reports required.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The firm did not submit the requirements /documents as per enclosure of Form 5. • The firm did not submit copy of contract manufacturing agreement. • The fee has been deposited by M/s Biomark Pharmaceuticals.
	Decision of 317th meeting: Deferred for submission of: • requirements /documents as per enclosure of Form 5. • copy of contract manufacturing agreement. • Application Fee of Rs. 75,000/-	
	Firm's response: Firm has submitted following: • Complete enclosures of Form 5. • Contract agreement between M/s Sapient pharma and M/s Bio Mark Pahrma • GMP certificate of Bio-mark issue don basis of inspection conducted on 13-02-2020	
	Decision: Approved with Innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

	• **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore.**	
1368.	Name and address of manufacturer/ Applicant	M/s Life Pharmaceutical Company, 24-III, Industrial Estate, Multan.
	Brand Name + Dosage Form + Strength	LYCLEAR Lotion 5% w/v
	Composition	Each ml contains: Permethrin….50mg (5% w/v)
	Diary No. Date of R & I & fee	Dy. No.5988 dated 23-05-2011, Rs. 8,000/- challan dated 21-05-2011 (Photocopy), Dy. No.21664 dated 20-11-2017 Differential fee Rs. 12,000/- vide challan No.0304345 dated 15-11-2017 (Photocopy) "Duplicate dossier, R & I verified"
	Pharmacological Group	Scabicide
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved as Permethrin Lotion 5% w/w TGA Australia approval as (QUELLADA SCABIES TREATMENT LOTION permethrin 50mg/mL bottle)
	Me-too status	Dynarix (Permethrin) 5% Lotion (Each gm contains permethrin 50mg) of M/s Dynatis Pakistan Ltd. Lahore. Registration No. 099996
	GMP status	GMP certificate dated 23-08-2021 issued based on evaluation (DML renewal) conducted on 16-06-2021.
	Remarks of the Evaluator (PEC-XVII)	• External liquid preparation section (General) Section approval granted vide letter No. F. 1-30/84-Lic (Vol.I) dated 27-04-2017. • V R & I record verified. Details incorporated in relevant column above.
	Decision: Deferred for submission of following documents: • Confirmation of required manufacturing facility / section from Licensing Division. • Submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 for correction/pre-approval change/ in product specifications.	
	Firm's response: Firm has submitted GMP certificate issued on basis of inspection conducted on 16-06-2021, declaring availability of External Liquid preparation general section and Cream/ointment section. Frim has also referred to their already registered product of Lindane lotion 1% vide registration# 060636.	
	Decision: Deferred for confirmation from Licensing Division for availability of required manufacturing facility for applied dosage form of "Lotion".	

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New cases

1369.	Name, address of Applicant / Marketing Authorization Holder	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 6506 dated 09-03-2022
	Details of fee submitted	Rs.30,000/- dated 25-01-2022
	The proposed proprietary name / brand name	**Caracip 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin as hydrochloride …….. 500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO 500mg tablet by Bayer Healthcare USFDA Approved.
	For generic drugs (me-too status)	CFLOX 500 mg Tablet by Global
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, Capsule, Dry powder and Ampule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Saakh Pharma Pvt. Ltd., Plot # C-7/1, North Western Industrial Zone Port Qasim, Karachi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Ciproxin 500mg Tablets by Bayer Healthcare performing quality tests. CDP has been performed against the same brand that is Ciproxin 500mg Tablet by Bayer Healthcare in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma Pvt. Ltd., Plot # C-7/1, North Western Industrial Zone Port Qasim, Karachi		
API Lot No.	21GN90039		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	07-2021	07-2021	07-2021
No. of Batches	03		

1370.	Name, address of Applicant / Marketing Authorization Holder	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Name, address of Manufacturing site.	M/s.Carer pharmaceuticals plot No.27 RCCI Industrial estate Rawat Islamabad Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 6505 dated 09-03-2022
	Details of fee submitted	Rs.30,000/- dated 25-01-2022
	The proposed proprietary name / brand name	**Caracip 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin as hydrochloride …….. 250mg
	Pharmaceutical form of applied drug	Film coated tablet

	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CIPRO 250mg tablet by Bayer Healthcare USFDA Approved.
	For generic drugs (me-too status)	CFLOX 250 mg Tablet by Global, Reg. No. 084114
	GMP status of the Finished product manufacturer	New license granted on 07/06/2021 Tablet, Capsule, Dry powder and Ampule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Saakh Pharma Pvt. Ltd., Plot # C-7/1, North Western Industrial Zone Port Qasim, Karachi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (P11-001, P11-002, P11-003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Ciproxin 250mg Tablets by Bayer Healthcare performing quality tests. CDP has been performed against the same brand that is Ciproxin 250mg Tablet by …Bayer Healthcare in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8).

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s Saakh Pharma Pvt. Ltd., Plot # C-7/1, North Western Industrial Zone Port Qasim, Karachi		
API Lot No.	21GN90039		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	07-2021	07-2021	07-2021
Date of Initiation	18-07-2021	18-07-2021	18-07-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 83/2020-DRAP(K) issued by CFDA valid till 23/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Local purchase from SAAKH PHARMA KARACHI.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4.1	• Drug substance specifications & analytical procedure submitted form M/s Saakh Pharma, mention both USP & BP as reference. Clarification shall be submitted for claiming both standards as specifications. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the	Drug substance manufacturer has claimed that the drug substance complies both BP & USP monograph while M/s Carer Pharma has adopted USP specifications and analytical procedure for Drug substance.

	Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Submitted.
3.2.S.4.4	Submitted COA of drug substance mentions manufacturing date as December 2021, whereas date of analysis is declared as 25-06-2021.	Firm has declared it a typographical error and has submitted revised COA.
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted.
3.2.S.7	Long term stability studies data of 3 batches for drug substance shall be submitted form M/s Saakh pharma.	Firm has submitted long term stability studies data as per Zne IVa of three batches till 48 months.
3.2.P.2.2.1	CDP studies have been performed with two sampling time points only whereas relevant guidelines recommend at least three sampling time points.	
3.2.P.5.3	• Performance of precision & specificity parameter shall be submitted for analytical method verification studies. • Results of accuracy parameter are not as per the specified concentrations in the method.	Firm has submitted revised analytical method verification studies with performance of precision & specificity parameter.
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted.
3.2.P.8.3	• Analytical results mentioned in stability summary sheets are different from that declared in batch analysis COA. • Manufacturing date mentioned on Stability summary sheets is different form that declared on COAs. • UV wavelength declared on submitted chromatograms of Assay analysis is different from that mentioned in method. • HPLC chromatograms have been submitted from dissolution analysis whereas USP monograph recommends USP spectrophotometric method. • Complete batch manufacturing record shall be submitted for all three stability batches.	• Firm has submitted revised stability summary sheets declaring results & manufacturing date as per submitted COA. • Firm has submitted complete batch manufacturing records of all three stability batches.

Decision: Registration Board approved the applications of Caracip 500mg tablet and Caracip 250mg tablet with change of brand name. Registration letter will be issued upon submission of following:

- **CDP studies against the innovator product as per time points recommended by relevant guidelines**
- **Performance of stability studies with revised analyticalmethod as per USP at next time point of long term stability studies.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

b. Deferred cases

1371.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 26376 dated 19-09-2022
	Details of fee submitted	Rs.30,000/- dated 12-09-2022
	The proposed proprietary name / brand name	**V-Drop 5mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml ampoule contains: Vitamin D3 …….5mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	1ml(1x1,s)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Approved by ANSM of France.**
	For generic drugs (me-too status)	Indrop D Injection M/s Neutro Pharmaceutical Pvt Ltd Pakistan., Reg. No. 023170
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., Weichend Jinhe East Road, Shifang City, Sichuan Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies	Stability study conditions: Real time: 5˚C ± 3˚C Accelerated: 25˚C ± 2˚C / 60% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Indrop D injection by M/s Neutro.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Sichuan Province Yuxin Pharmaceutical Co., Ltd., Weichend Jinhe East Road, Shifang City, Sichuan Province, China.		
API Lot No.	VD3220513		
Description of Pack (Container closure system)	Glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML# SC 20160429 issued by NMPA valid till 18-10-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2. S.4.1	Drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies Shall Be Submitted from M/s May & Baker.	Firm has submitted analytical method verification report for the drug substance and has referred to USP monograph of Cholecalciferol for the drug substance specifications and analytical procedure.
3.2.S.4.4	COA of relevant batch of API from drug substance manufacturer shall be submitted used for manufacturing of drug product trial batches.	Submitted.
3.2.P.5.4	Submitted COA declares average volume as 5ml. Justification shall be submitted in this regard.	It is a typo error, average volume is mentioned for 5 number of units.
3.2.P.6	COA of reference/working standard shall be submitted.	Submitted.
3.2.P.8	• Complete batch manufacturing record of three stability batches shall be submitted. • GMP certificate of the drug substance manufacturer shall be submitted. • Documents confirming procurement of drug substance shall be submitted.	• Firm has submitted batch manufacturing record for three stability batches. • Firm has submitted copy of DML# 20160429 valid till 18-10-2025 for the drug substance manufacturer. • Firm has stated that drug substance was borrowed from M/s Global Pharma and has submitted commercial invoice in attested by AD DRAP I&E Islamabad dated 27-08-2021 in name of M/s Global Pharma for import to 15Kg Vitamin D3.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued upon verification of API loan letter by M/s Global Pharmaceuticals.**

Case no. 03 New Registration applications on Form 5F (Human)

a. New Cases (Human)

1372.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., 16, K.O.C.H.S. Amir Khusro Road, Karachi-75350, Pakistan**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32728 dated 01-12-2021
	Details of fee submitted	Rs.20,000/- dated 16-04-2021 & Rs.10,000/- dated 20-09-2021
	The proposed proprietary name / brand name	SciAmpa-M 5+500 mg tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin……..5mg Metformin HCl……..500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-hyperglycemic agents (A10BD20)
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	14's & 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Synjardy 5+500 mg tablet **(EMA** Approved).
	For generic drugs (me-too status)	XENGLU-MET 5MG +500mg Tablet of Hilton Pharma (Reg #093102)
	GMP status of the Finished product manufacturer	Renewal of license granted on 01/06/2021 Tablet, Capsule, Ointment/Cream, Sachet, Dry Powder Inhalaer & Dry Powder suspension (General) sections approved. Last inspection conducted on 16-11-2021 and concludes that firm was considered to be operating at Good level of compliance
	Name and address of API manufacturer.	**API manufacturer of Empagliflozin** Name: Fuxin Long Rui Pharmaceutical CO., Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **API manufacturer of Metformin Hydrochloride** Name: Shouguang Fukang Pharmaceutical Co., Ltd. Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of both API at accelerated as well as real time conditions. The real time stability data of Empagliflozin conducted at 30±2°C, 65%±5% RH. The stability study data is till 26 months.

		The real time stability data of Metformin hydrochloride conducted at 30±2°C, 75%±5% RH. The stability study data is till 60 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Compartitive dissolution profile against Xenglu Met 5+500mg Tablet of Hilton Pharma
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

STABILITY STUDY DATA

Manufacturer of API	**API manufacturer of Empagliflozin** Name: Fuxin Long Rui Pharmaceutical CO., Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **API manufacturer of Metformin Hydrochloride** Name: Shouguang Fukang Pharmaceutical Co., Ltd. Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area		
API Lot No.	0000006044 / 0000006965		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	201B20	202B20	203B20
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	25-11-2020	26-11-2020	26-11-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Glusimet XR 50/500mg Tablets & Glusimet XR 50/1000mg Tablets which was conducted on 16th July, 2020 and was presented in 296th meeting of Registration Board held on 8th - 10th September, 2020. According to the report following points were confirmed. □ The firm has 21 CFR compliant HPLC software □ The firm has audit trail reports available. □ The firm possesses stability chambers with digital data loggers.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin** Copy of DML certificate No. Liao20150233 issued by FDA of Liaoning Province valid till 20/12/2022. **Metformin HCl:** Copy of GMP certificate No. SD20190888 issued by CFDA valid till 12/03/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of form 5, invoice (invoice# HN19011801-H) Dated: 18-01-2020, cleared by DRAP Karachi office dated 30-01-2020 specifying import 10Kg Empagliflozin (Batch# E-20190920-D02-E06-01). **Metformin HCl:** Firm has submitted copy of Form 5 & invoice (invoice# 20FK04Z4106B) Dated: 05-05-2020 from Shouguang Fukang Pharmaceutical Co., Ltd. cleared, cleared by DRAP Karachi office dated 30-01-2020 specifying import 3000Kg Metformin HCl (Batch# A-32612004031 & A-32612004032).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

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

1373	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Capsule general section
	Dy. No. and date of submission	Dy.No 29993 dated 03-11-2021
	Details of fee submitted	Rs.75,000/- dated 22-10-2021

	The proposed proprietary name / brand name	**Sildos 8mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Silodosin…….8mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Siloon capsule of M/s Genix
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd, No. 15 Donghai 5th Avenue Zhejiang Provincial Chmeical and Medical Raw Materials Base Linhai Zone Taizhou Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of Steglujan tablet
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.
1374	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer

		☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 29992 dated 03-11-2021
	Details of fee submitted	Rs.75,000/- dated 22-10-2021
	The proposed proprietary name / brand name	**Sildos 4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Silodosin…4mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Silon capsule by M/s Genix
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd, No. 15 Donghai 5th Avenue Zhejiang Provincial Chmeical and Medical Raw Materials Base Linhai Zone Taizhou Zhejiang China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of rapaflo capsule
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd, No. 15 Donghai 5th Avenue Zhejiang Provincial Chmeical and Medical Raw Materials Base Linhai Zone Taizhou Zhejiang China.
API Lot No.	Batch no. 13000-171201
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (30's)
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1, 2, 3, 4 & 6 (months)

Sildos 4mg capsule

Batch No.	19SB-209-01	19SB-209-02	19SB-209-03
Batch Size	1500	1500	1500
Manufacturing Date	10.2019	10.2019	10.2019

Sildos 8mg capsule

Batch No.	19SB-212-01	19SB-213-02	19SB-214-03
Batch Size	1500	1500	1500
Manufacturing Date	10.2019	10.2019	10.2019
No. of Batches	06		

a	Reference of previous approval of applications with stability study data of the firm (if any)	--
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., issued by China Food and Drug Administration valid till 14-03-2023
c	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 0.1Kg silodosin dated 24.01.2018. The invoice is signed by AD (I&E) DRAP Karachi office on 06.02.2018..
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval in 297th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 297th meeting on Form 5D, based on the stabiltiy data as per checklist for "Exemption from On-site inspection". The details of the already considered product in 297th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi	
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi	
Brand Name	Silpro 4mg capsule	Silpro 8 mg capsule
Batch No. of drug product	19SB-209-01 19SB-209-02 19SB-209-03	19SB-212-01 19SB-213-02 19SB-214-03
Case No.	532	533
Registration Board meeting	297th meeting of Registration Board held on 12 -15 January, 2021	

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 289th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Synjardy tablet.
  - Complete batch manufacturing record of three stability batches.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

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

- Analytical method verification studies for drug substance performed by the drug product manufacturer shall be submitted.

Decision: Registration Board approved applications of Sildos 4mg Capsule & Sildos 8mg Capsule.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

1375	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 30264 dated 05-11-2021
	Details of fee submitted	Rs.75,000/- dated 22-09-2021
	The proposed proprietary name / brand name	**Erglif-S 15/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. To Ertugliflozin……15mg Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin…….100mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	**Ertugliflozin:** Shanghai Pharma Group Changzhou kony Pharmaceuticals Co., Ltd China Daixi street, Luoyang town, Wujin District, Changzhou, Jiangsu, China **Sitagliptin:** M/s Zheijiang Yengtai Pharmaceutical Co., Ltd, China No1 Donghai 4th avenue zheijiang provincial chemical and medical raw material base Linhai zone, Linhai city Zhejiang province China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of Steglujan tablet
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.
1376	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 29991 dated 03-11-2021
	Details of fee submitted	Rs.75,000/- dated 22-09-2021
	The proposed proprietary name / brand name	**Erglif-S 5/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. To Ertugliflozin…….5mg Sitagliptin Phosphate Monohydrate Eq. To Sitagliptin…….100mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	**Ertugliflozin:** Shanghai Pharma Group Changzhou kony Pharmaceuticals Co., Ltd China Daixi street, Luoyang town, Wujin District, Changzhou, Jiangsu, China **Sitagliptin:** M/s Zheijiang Yengtai Pharmaceutical Co., Ltd, China No1 Donghai 4th avenue zheijiang provincial chemical and medical raw material base Linhai zone, Linhai city Zhejiang province China

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of Steglujan tablet
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA

Manufacturer of API	Ertugliflozin: Shanghai Pharma Group Changzhou kony Pharmaceuticals Co., Ltd China Daixi street, Luoyang town, Wujin District, Changzhou, Jiangsu, China Sitagliptin: M/s Zheijiang Yengtai Pharmaceutical Co., Ltd, China No1 Donghai 4th avenue zheijiang provincial chemical and medical raw material base Linhai zone, Linhai city Zhejiang province China
API Lot No.	Ertugliflozin: ETG20180901 Sitagliptin: 1827-0001-20015
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1, 2, 3, 4 & 6 (months)

ERGLIF-S TABLET 5MG/100MG

Batch No.	20SB-004-01	20SB-005-02	20SB-006-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	01-2020	01-2020	01-2020

Date of Initiation		24-02-2020	24-02-2020	24-02-2020
ERGLIF -S TABLET 15MG/100MG				
Batch No.		20SB-001-01	20SB-002-02	20SB-003-03
Batch Size		1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date		01-2020	01-2020	01-2020
Date of Initiation		17-02-2020	17-02-2020	17-02-2020
No. of Batches		06		
a	Reference of previous approval of applications with stability study data of the firm (if any)		--	
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		**Ertugliflozin:** Firm has submitted copy of GMP certificate (No. JS20170734) issued by CFDA China. The certificate is valid till 25-12-2022. **Sitagliptin:** The copy of cGMP Certificate valid up to 28-06-2023 for M/s. Zheijang Yongtai Pharmaceutical Co., Ltd., Zheijiang Province is provided.	
c	Documents for the procurement of API with approval from DRAP (in case of import).		**Ertugliflozin:** Firm has submitted copy of commercial invoice cleared dated 12-10-2018 specifying import of 500g Ertugliflozin. The invoice is signed by AD (I&E) DRAP Karachi office dated 12-10-2018. **Sitagliptin:** Firm has submitted copy of commercial invoice cleared dated 29-10-2019 specifying import of 300kg Sitagliptin phosphate monohydrate. The invoice is signed by AD (I&E) DRAP Karachi.	
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Submitted	
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.		Submitted	
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Submitted	

Remarks of Evaluator[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval IN 317th meeting of Registration Board. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 317th meeting on Form 5D, based on the stabiltiy data as per checklist for "Exemption from On-site inspection". The details of the already considered product in 317th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi	
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi	
Brand Name	ERTOZIN-S Tablet 5mg/100mg	ERTOZIN-S Tablet 15mg/100mg
Batch No. of drug product	20SB-004-01 20SB-005-02 20SB-006-03	20SB-001-01 20SB-002-02 20SB-003-03
Case No.	11	12

Registration Board meeting	317th meeting of Registration Board held on 16 -17 May, 2022

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 289th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Synjardy tablet.
  - Complete batch manufacturing record of three stability batches.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

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

- Analytical method verification studies for drug substance performed by the drug product manufacturer shall be submitted.

Decision: Registration Board approved applications of Erglif-S 15/100 mg Tablet & Erglif-S 5/100 mg Tablet.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

1377	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 29316 dated 27-10-2021
	Details of fee submitted	Rs.75,000/- dated 12-10-2021
	The proposed proprietary name / brand name	**Paglif-M XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…….5mg (As Immediate Release Coating) Metformin HCl……1000mg (As Extended Release Coating)

	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Emglif-M XR tablet by M/s Genix Pharma
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** M/s Wanbury Ltd., India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of Synjardy tablet
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA

Manufacturer of API	Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China Metformin HCl: M/s Wanbury Ltd., Dist. Raigad, Maharashtra State., India
API Lot No.	Empagliflozin Lot #: EGLZ-RD20171101A Metformin Hydrochloride Lot #: MT00600118
Description of Pack (Container closure system)	Alu-Alu Blister Pack
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH

		Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.		18SB-106-01	18SB-107-02	18SB-108-03
Batch Size		1500 tablets	1500 tablets	1500 tablets
Manufacturing Date		06-2018	06-2018	06-2018
No. of Batches		03		
Administrative Portion				
a	Reference of previous approval of applications with stability study data of the firm (if any)	--		
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The DML # 20160622 valid till 2026 is provided for RUYUAN HEC Pharm Co., Ltd **Metformin HCl:** Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India		
c	Documents for the procurement of API with approval from DRAP (in case of import).	**For Empagliflozin:** Copy of commercial Invoice declaring following information on it: Invoice No: WIS170152 Attested by: ADC Karachi Attested on: 07-12-2017 Quantity: 0.75 Kg From: M/s WIS Pharmatech Co., Ltd. Factory, Manufactured by M/s Ruyuan HEC Pharm Co., Ltd. China. **For Metformin HCl:** Copy of commercial Invoice declaring following information on it: Invoice No: EXP/92001577/ 17-18 Attested by: ADC Karachi Attested on: 30-1-2018 Quantity: 5000 Kg From: M/s Wanbury Limited, India.		
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted		
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Evaluator[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval 19-10-2020. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 293rd meeting on Form 5D, based on the stabiltiy data as per checklist for

"Exemption from On-site inspection". The details of the already considered product in 293rd meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Empag M 5mg + 1000mg XR Tablets
Batch No. of drug product	18SB-103-01 18SB-104-02 18SB-105-03
Case No.	2453
Registration Board meeting	293rd meeting of Registration Board held on 6 -8 January, 2020

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 289th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Synjardy tablet.
  - Complete batch manufacturing record of three stability batches.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

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

- Analytical method verification studies for drug substance performed by the drug product manufacturer shall be submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

1378	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 29430 dated 28-10-2021

	Details of fee submitted	Rs.75,000/- dated 23-09-2021
	The proposed proprietary name / brand name	**Paglif-M 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…….12.5mg Metformin HCl……1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Emglif-M tablet by M/s Genix Pharma
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** M/s Wanbury Ltd., India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the reference product of Synjardy tablet
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.
STABILITY STUDY DATA		

Manufacturer of API	Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China Metformin HCl: M/s Wanbury Ltd., Dist. Raigad, Maharashtra State., India		
API Lot No.	Empagliflozin: EGLZ-RD20171101A Metformin hydrochloride: MT00600118, MT00610118, MT00620118 MT00630118		
Description of Pack (Container closure system)	Alu-Alu Blister Pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.	18SB-103-01	18SB-103-02	18SB-103-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
No. of Batches	03		

Administrative Portion

a	Reference of previous approval of applications with stability study data of the firm (if any)	--
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The DML # 20160622 valid till 2026 is provided for Ruyuan HEC Pharm Co., Ltd **Metformin HCl:** Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India
c	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 07-12-2017 for the import of Empagliflozin has been attached. **Batch No.** / **Invoice No.** / **Quantity Imported.** EGLZ-RD20171101A / WIS170152 / 750gm **Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 30-01-2018 for the import of Metformin HCl has been attached.
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval 19-10-2020. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 289th meeting on Form 5D, based on the stabiltiy data as per checklist for "Exemption from On-site inspection" of same batches of drug product as submitted in the instant case. The details of the already considered product in 289th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Empag-M Tablet 12.5mg/1000mg
Batch No. of drug product	18SB-103-01 18SB-103-02 18SB-103-03
Case No.	404
Registration Board meeting	289th meeting of Registration Board held on 14-16 May, 2019

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 289th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Synjardy tablet.
  - Complete batch manufacturing record of three stability batches.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

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

Analytical method verification studies for drug substance performed by the drug product manufacturer shall be submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

1379	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 29429 dated 28-10-2021
	Details of fee submitted	Rs.75,000/- dated 23-09-2021
	The proposed proprietary name / brand name	**Paglif-M 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…….12.5mg Metformin HCl……500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Emglif-M tablet by M/s Genix Pharma
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** M/s Wanbury Ltd., India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of Synjardy tablet
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability,

<table>
<tr><td></td><td></td><td colspan="3">specificity, linearity, accuracy, precision-repeatability.</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td colspan="3">Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China
Metformin HCl: M/s Wanbury Ltd., Dist. Raigad, Maharashtra State., India</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">Empagliflozin: EGLZ-RD20171101A
Metformin hydrochloride: MT00600118, MT00610118, MT00620118 MT00630118</td></tr>
<tr><td colspan="2">Description of Pack (Container closure system)</td><td colspan="3">Alu-Alu Blister Pack</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time : 30˚C ± 2˚C / 65% ± 5% RH
Accelerated: 40˚C ± 2˚C / 75% ± 5% RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0,1,2,3,4,6 (month)
Real Time: 0,3,6 (month)</td></tr>
<tr><td colspan="2">Batch No.</td><td>18SB-100-01</td><td>18SB-101-02</td><td>18SB-102-03</td></tr>
<tr><td colspan="2">Batch Size</td><td>1500 tablets</td><td>1500 tablets</td><td>1500 tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>04-2018</td><td>04-2018</td><td>04-2018</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="5">Administrative Portion</td></tr>
<tr><td>a</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">--</td></tr>
<tr><td>b</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Empagliflozin:
The DML # 20160622 valid till 2026 is provided for RUYUAN HEC Pharm Co., Ltd
Metformin HCl:
Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India</td></tr>
<tr><td>c</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Empagliflozin:
Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 07-12-2017 for the import of Empagliflozin has been attached.
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th></tr><tr><td>EGLZ-RD20171101A</td><td>WIS170152</td><td>750gm</td></tr></table>
Metformin HCl:
Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 30-01-2018 for the import of Metformin HCl has been attached.</td></tr>
<tr><td>d</td><td>Data of stability batches will be supported by attested respective documents like chromatograms,
Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Submitted</td></tr>
<tr><td>e</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Submitted</td></tr>
</table>

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

Remarks of Evaluator[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval 19-10-2020. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 289th meeting on Form 5D, based on the stabiltiy data as per checklist for "Exemption from On-site inspection" of same batches of drug product as submitted in the instant case. The details of the already considered product in 289th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Empag-M Tablet 12.5mg/500mg
Batch No. of drug product	18SB-100-01 18SB-101-02 18SB-102-03
Case No.	403
Registration Board meeting	289th meeting of Registration Board held on 14-16 May, 2019

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 289th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Synjardy tablet.
  - Complete batch manufacturing record of three stability batches.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

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

Analytical method verification studies for drug substance performed by the drug product manufacturer shall be submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

1380	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**

	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 28459 dated 15-10-2021
	Details of fee submitted	Rs.75,000/- dated 23-09-2021
	The proposed proprietary name / brand name	**Paglif-M 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…….5mg Metformin HCl…….1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Emglif-M tablet by M/s Genix Pharma
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** M/s Wanbury Ltd., India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of Synjardy tablet
	Analytical method validation/verification of product	Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA

Manufacturer of API	Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China Metformin HCl: M/s Wanbury Ltd., Dist. Raigad, Maharashtra State., India		
API Lot No.	Empagliflozin: EGLZ-RD20171101A Metformin hydrochloride: MT00600118, MT00610118, MT00620118 MT00630118		
Description of Pack (Container closure system)	Alu-Alu Blister Pack		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.	18SB-097-01	18SB-097-01	18SB-097-01
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
No. of Batches	03		

Administrative Portion

a	Reference of previous approval of applications with stability study data of the firm (if any)	--
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The DML # 20160622 valid till 2026 is provided for RUYUAN HEC Pharm Co., Ltd **Metformin HCl:** Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India
c	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 07-12-2017 for the import of Empagliflozin has been attached. **Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 30-01-2018 for the import of Metformin HCl has been attached.
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

Batch No.	**Invoice No.**	**Quantity Imported.**
EGLZ-RD20171101A	WIS170152	750gm

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

Remarks of Evaluator[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval 19-10-2020. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 289th meeting on Form 5D, based on the stabiltiy data as per checklist for "Exemption from On-site inspection" of same batches of drug product as submitted in the instant case. The details of the already considered product in 289th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Empag-M Tablet 5mg/1000mg
Batch No. of drug product	18SB-097-01 18SB-098-02 18SB-099-03
Case No.	405
Registration Board meeting	289th meeting of Registration Board held on 14-16 May, 2019

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 289th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Synjardy tablet.
  - Complete batch manufacturing record of three stability batches.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

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

Analytical method verification studies for drug substance performed by the drug product manufacturer shall be submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

1381	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer

		☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Tablet general section
	Dy. No. and date of submission	Dy.No 28458 dated 15-10-2021
	Details of fee submitted	Rs.75,000/- dated 23-09-2021
	The proposed proprietary name / brand name	**Paglif-M 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…….5mg Metformin HCl…….500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti Diabetic
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Emglif-M tablet by M/s Genix Pharma
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021
	Name and address of API manufacturer.	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China **Metformin hydrochloride:** M/s Wanbury Ltd., India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

<table>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Pharmaceutical Equivalence & CDP have been established against the referenc eproduct of Synjardy tablet</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Method validation studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td colspan="3">Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China
Metformin HCl: M/s Wanbury Ltd., Dist. Raigad, Maharashtra State., India</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">Empagliflozin: EGLZ-RD20171101A
Metformin HCl: MT00600118</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister foil with unit carton</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Real Time: 30˚C ± 2˚C / 65% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0,1,2,3,4,6 (month)
Real Time: 0,3,6 (month)</td></tr>
<tr><td colspan="2">Batch No.</td><td>18SB-093-01</td><td>18SB-095-02</td><td>18SB-096-03</td></tr>
<tr><td colspan="2">Batch Size</td><td>1500 Tablets</td><td>1500 Tablets</td><td>1500 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>04-2018</td><td>04-2018</td><td>04-2018</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="5">Administrative Portion</td></tr>
<tr><td>a</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">--</td></tr>
<tr><td>b</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Empagliflozin:
Copy of GMP certificate (2017029) issued by M/s Shaoguan Food & Drug Administration, valid upto 21-01-2019 for M/s Ruyuan HEC Pharm Co., Ltd.
Metformin HCl:
Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India</td></tr>
<tr><td>c</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Empagliflozin:
Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 07-12-2017 for the import of Empagliflozin has been attached.
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th></tr><tr><td>EGLZ-RD20171101A</td><td>WIS170152</td><td>750gm</td></tr></table>Metformin HCl:
Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 30-01-2018 for the import of Metformin HCl has been attached.</td></tr>
<tr><td>d</td><td>Data of stability batches will be supported by attested respective documents like chromatograms,
Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Submitted</td></tr>
</table>

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

Remarks of Evaluator[II]:

- The applied formulation to be manufactured by M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi have already been granted approval 19-10-2020. The case of the applied formulation of M/s Genix Pharma Private Limited 44-45B Korangi Creek Road Karachi, was considered and approved by Registration Board in its 289th meeting on Form 5D, based on the stabiltiy data as per checklist for "Exemption from On-site inspection" of same batches of drug product as submitted in the instant case. The details of the already considered product in 289th meeting are as follows:

Applicant firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Manufacturer firm	M/s Genix Pharma Private Limited 44-45B Korangi creek Road Karachi
Brand Name	Empag-M Tablet 5mg/500mg
Batch No. of drug product	18SB-093-01, 18SB-095-01, 18SB-096-01,
Case No.	406
Registration Board meeting	289th meeting of Registration Board held on 14-16 May, 2019

- Following data had been evaluated earlier in the above referred application of M/s Genix Pharma approved in 289th meeting:
  - Method used for analysis of API along with COA.
  - Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
  - Record of comparative dissolution data against the reference product of Synjardy tablet.
  - Complete batch manufacturing record of three stability batches.
  - Reports of stability studies of API from manufacturer.
  - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

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

Analytical method verification studies for drug substance performed by the drug product manufacturer shall be submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**

1382	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi

	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Beta-Lactam (penem) section
	Dy. No. and date of submission	Dy.No 27307 dated 04-10-2021
	Details of fee submitted	Rs.75,000/- dated 29-09-2021
	The proposed proprietary name / brand name	**ERTAP 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ertapenem sodium equivalent to Ertapenem ……. 1gm
	Pharmaceutical form of applied drug	White to light yellow powder
	Pharmacotherapeutic Group of (API)	Anti-bacterial
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	**Invanz Injection** by Merck & CO.,INC , FDA Approved.
	For generic drugs (me-too status)	Ernem Injection by M/s Genix Pharma Reg no: 081179
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021 Capsule section approved.
	Name and address of API manufacturer.	**SAVIOR LIFETEC CORPORATION,** 29, Ke-Jhong Rd., Chunan Chen, Miaoli, County 35053, Taiwan, R.O.C.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Invanz Injection**
	Analytical method validation/verification of product	Method verification studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA

Manufacturer of API	**SAVIOR LIFETEC CORPORATION,** 29, Ke-Jhong Rd., Chunan Chen, Miaoli, County 35053, Taiwan, R.O.C.		
API Lot No.	80S019AA001		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated:0,3 & 6(Months) Real Time: 0,3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	001I042	002I042	003I042
Batch Size	7434 vials	7558 vials	7791 vials
Manufacturing Date	09-2017	02-2018	07-2018
Date of Initiation	15-10-2017	15-03-2018	29-08-2018
No. of Batches	03		

Administrative Portion

a	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
c	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase invoice No. S180201 attested by DRAP dated 06.06.2018 is submitted
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section#	Observation	Firm's response
1.6.5	Valid GMP certificate of drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP issued by Ministry of Health & Welfare, Taiwan, valid till 23/01/2024
3.2.S.5	• Justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard insetad of the pure Eertapenem sodium. • Submitted drug substance analytical procedure mandates use of Ertapenem as working standard whereas submitted COA is of Ertapenem sodium lyophilized powder.	We received working standard Ertapenem sodium as lyophilized powder from supplier. Saviour Lifetech Corporation herenby confirmed that ertapenem sodiumlyophilized powder is more suitable as workingstandrad than Ertapneem sodium due to its longer retest period. 24 m. In thi scase, ertapaneme sodiumlyophilized powder can be used in a more reliable way. The actual assay can be calibrated by method calculation. The ertapenem sodium lyophilized powder is preferable as working standard by our expert's persepective. Therefore, the submitted COA of Ertapneem sodiumlyophilized powder was provide din 3.2.S.5.
3.2.S.7.3	Justification shall be submitted for conducting drug substance stability studies at refrigerating conditions.	As Ertapenem sodium lyophilized powder will b edirectly filled in to vial, the quality of Ertapenem sodium lyophilized powder is very critical and should be preserved in conservative way at lower temperature. Therefore based on this concept we chose to conduct the stability studies of drug substance in storage conditions of 5 $\pm$3^{o}C to ensure quality.
3.2.P.1	• Justification shall be submitted for proposed fill weight per vial of Eetapenem sodium considering the actual content of sodium declared in the drug substance analysis and content of sodium bicarbonate in the drug substance. • Details of accompanying reconstitutuin diluent shall be submitted.	• The justification is as under: 1gmof Ertapenem for injection (Bulk sterile) will contain following: Ertapenem monosodium ….. 809.60mg Sodium bicarbonate …….. 135.40mg NaOH…….. 55.0mg Total……. 1000.0mg Factor = Ertapenem sodium/Ertapneem = 497.50/475.5 = 1.046 Then, 1000.0mg x 1.046 1046.00mg appx. 1050mg. The filled weight of 1340mg against the determined potency of 78.20% of drug substance eis justified as per above referred calculations. • Diluent is not the part of finished pack.
3.2.P.2.2.1	• Submit justification of not performing tests of pH, sterility, water content, endotoxins and particulate matter in Pharmaceutical equivalence studies.	Due to insufficient qanity of innovator sample, we performed appearance, identification and Assay. As per requirements from DRAp, we performed all test on new innovator sample "Invanz injection".
3.2.P.2.6	• Comaptibility studies with the reconstitution diluent shall be submitted.	Submitted with 0.9% sodium chloride solution.
3.2.P.5	• Justification shall be submitted for not including tests of completeness and clarity of solution, pH, & water content in the drug product	The material Ertapenemm sodium is lyiophilized sterile powder and ready to fill material, we performed these test during API testing.

	specifications, as recommended by the Innovator product.	
3.2.P.6	• Justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard insetad of the pure Eertapenem sodium.	Same as above in section 3.2.S.6
3.2.P.8	• Justification shall be submitted for not performing tests of completeness and clarity of solution, pH, & water content during stability studies. • Complete batch manufacturing record shall be submitted for the three stability batches. • Microbial reports shall be submitted for the sterility testing during stability studies. • Documents confirming import of drug substance with approval form DRAP shall be submitted.	• The material Ertapenemm sodium is lyiophilized sterile powder and ready to fill material, we performed these test during API testing in order to reduce the test on finished product testing and on basis of supplier stability studies of real time as well as accelerated. It is concluded that the API is stable throghot the shelf life. • BMRs have been submitted.

Decision: Deferred for scientific justification for:

- **Use of Ertapenem sodium lyophilized powder as working standard insetad of the pure Eertapenem sodium since submitted drug substance analytical procedure mandates use of Ertapenem as working standard whereas submitted COA is of Ertapenem sodium lyophilized powder.**
- **Not including tests of ests of completeness and clarity of solution, pH, & water content in drug product specifications and stability studies.**

1383	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	GMP granted on 07/10/2021 Capsule section approved.
	Dy. No. and date of submission	Dy.No 32862 dated 15-12-2021
	Details of fee submitted	Rs.75,000/- dated 15-11-2021 & Rs.75,000/- dated 16-08-2021
	The proposed proprietary name / brand name	**Dexzole 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delayed Release Capsule Contains: Dexlansoprazole Delayed Release Pellets 22.5% Eq. to Dexlansoprazole …… 30mg
	Pharmaceutical form of applied drug	Round, Biconvex, Light Orange color, film coated tablet, engraved "GENIX" on one side & break line on other side.
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor (PPI)
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 30's, 50's, 60's, 100's
	Proposed unit price	As per PRC

	The status in reference regulatory authorities	By M/s Takeda Pharmaceuticals America, Inc , Dexilant Capsules 60mg (Delayed release Capsules) USFDA Approved.
	For generic drugs (me-too status)	By M/s SAMI Pharmaceuticals (pvt.) Ltd. Delanzo 60mg (Delayed release Capsules) Registration No. 089146
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021 Capsule section approved.
	Name and address of API manufacturer.	Alphamed Formulations Private Limited. (ready to fill pellets) Survey No.: 225, Sampanbole Village, Shamirpet Mandal, Ranga Reddy District, Telangana – 500 078, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Dexilant capsule 30mg** M/s Takeda Pharmaceuticals America, Inc. CDP is submitted.
	Analytical method validation/verification of product	Method verification studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA

Manufacturer of API	M/s Alphamed Formulations Private Limited. Survey No.: 225, Sampanbole Village, Shamirpet Mandal, Ranga Reddy District, Telangana – 500 078, India
API Lot No.	ABC082021001/B

Description of Pack (Container closure system)	Alu/alu blister		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated:0,3 & 6(Months) Real Time: 0,3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	003C209	004C209	005C209
Batch Size	200,000 Capsule	200,000 Capsule	200,000 Capsule
Manufacturing Date	08-2018	08-2018	09-2018
Date of Initiation	17-08-2018	17-08-2018	04-10-2018
No. of Batches	03		

1384	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer **☒ Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	GMP granted on 07/10/2021 Capsule section approved.
	Dy. No. and date of submission	Dy.No 32862 dated 15-12-2021
	Details of fee submitted	Rs.75,000/- dated 15-11-2021 & Rs.75,000/- dated 16-08-2021
	The proposed proprietary name / brand name	**Dexzole 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delayed Release Capsule Contains: Dexlansoprazole Delayed Release Pellets 22.5% Eq. to Dexlansoprazole …… 60mg
	Pharmaceutical form of applied drug	Round, Biconvex, Light Orange color, film coated tablet, engraved "GENIX" on one side & break line on other side.
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor (PPI)
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	7's, 10's, 14's, 20's, 30's, 50's, 60's, 100's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	By M/s Takeda Pharmaceuticals America, Inc , Dexilant Capsules 60mg (Delayed release Capsules) USFDA Approved.
	For generic drugs (me-too status)	By M/s SAMI Pharmaceuticals (pvt.) Ltd. Delanzo 60mg (Delayed release Capsules) Registration No. 089146
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021

		Capsule section approved.
	Name and address of API manufacturer.	Alphamed Formulations Private Limited. (ready to fill pellets) Survey No.: 225, Sampanbole Village, Shamirpet Mandal, Ranga Reddy District, Telangana – 500 078, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Dexilant capsule 60mg** M/s Takeda Pharmaceuticals America, Inc. CDP is submitted.
	Analytical method validation/verification of product	Method verification studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA

Manufacturer of API	M/s Alphamed Formulations Private Limited. Survey No.: 225, Sampanbole Village, Shamirpet Mandal, Ranga Reddy District, Telangana – 500 078, India
API Lot No.	ABC082021001/B
Description of Pack (Container closure system)	Alu/alu blister
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	Accelerated:0,3 & 6(Months)

		Real Time: 0,3, 6, 9 ,12,18 & 24 (Months)		
Batch No.		001C208	002C208	003C208
Batch Size		200,000 Capsule	200,000 Capsule	200,000 Capsule
Manufacturing Date		08-2018	08-2018	08-2018
Date of Initiation		06-08-2018	06-08-2018	06-08-2018
No. of Batches		03		
Administrative Portion				
a	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted		
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 3081/STORES/2019 issued by "Drug control administration Telangana" on 30-08-2019 valid for 3 years		
c	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase invoice: GE035/2018 , attested by DRAP, dated 03/07/2018 is submitted		
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		
Remarks of Evaluator[II]:				
Decision: Registration Board approved applications of Dexzole 30mg Capsule & Dexzole 60mg Capsule. Firm shall submit differential fee for import of pellets for each strength. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.**				
1385	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Rogen Pharmaceuticals Plot No. 30, Street # S-4, National Industrial Zone, Rawat, Islamabad**		
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad		
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 11-02-2019, wherein Liquid Ampoule general section is declared.		
	Dy. No. and date of submission	Dy.No 29539 dated 29-10-2021		

	Details of fee submitted	Rs.50,000/- dated 12-2021 & Rs.25,000/- dated 15-10-2021
	The proposed proprietary name / brand name	**Rogvit-D Injection 5mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Cholecalciferol ……. 5mg
	Pharmaceutical form of applied drug	Liquid Injection
	Route of administration	IM
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	**In-House**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by ANSM of France.
	For generic drugs (me-too status)	Sunny D Injection of M/s Scotmann Pharma (Reg.#063450)
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 11-02-2019
	Name and address of API manufacturer.	M/s FERMENTA BIOTECH LIMITED, Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $25^{O} \pm 2^{O}$ C /60% ± 5% RH for 6 months. The real time stability data is conducted at $5^{O}C \pm 3^{O}$ C.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence studies against the Indrop-D injection.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s FERMENTA BIOTECH LIMITED, Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India		
API Lot No.	CLC0420149		
Description of Pack (Container closure system)	Amber glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	0118412	1218408	1218409
Batch Size	40,000 ampoules	50,000 ampoules	50,000 ampoules
Manufacturing Date	01-2018	12-2018	12-2018
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate (Certificate# 2062043) of M/s FERMENTA BIOTECH LIMITED. Plot no. Z-109-B 7 C, SEZ-II, DAHEJ, TAL-VAGRA, Dahej, dist. Bharuch, Gujarat State, India issued BY Food 7 Drugs Control Administration, Gujarat, India valid up to 17-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#RV2010020173) approved by AD DRAP I&E Islamabad dated 11-11-2020 for the import of Cholelcalciferol from M/s FERMENTA BIOTECH LIMITED. Plot no. Z-109-B 7 C, SEZ-II, DAHEJ, TAL-VAGRA, Dahej, dist. Bharuch, Gujarat State, India
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	--
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted.

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.1	Differential fee for Rs. 25,000/- shall be submitted.	
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Submitted
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Submitted.
3.2.S.4.4	Provide results of analysis along with analytical record, of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / Active Pharmaceutical Ingredient manufacture.	Submitted
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted
3.2.S.7	Evidence of availability of cold storage facility in the raw material store shall be submitted, since the drug substance manufacturer has recommended storage of API at 2- 8°C.	Calibration Certificate is attached for evidence
3.2.P.3.3	Submitted manufacturing procedure neither includes step of terminal sterilization nor the aseptic filtration prior to the ampoule filling. Justification shall be submitted regarding how the sterility of product is ensured.	Firm has submitted BMRs declaring steps of sterilization.
3.2.P.4.1	Pharmacopoeial reference for the used excipient shall be submitted or else detailed specifications and analytical procedure shall be submitted for excipient used in the formulation.	Submitted.
3.2.P.5.1	• Submitted drug product specifications does not include test of "Uniformity of Dosage Units". • Justification shall be submitted for un-conventional Assay limits of "90% to 120%". • Test of sterility does not refer to any particular or general limits. • Submitted specification does not include test of sterility & endotoxin.	Firm has submitted revised specifications. Previously we were adding overage/excess quantity in formulation and that was the reason that we were giving the limit of 90-120% but currently we are not adding any excess and also the limit of BP for Cholecalciferol injection 7.5mg/ml which is 90-110% is followed for 5mg/ml injection. Revised SOP of product of Shine D injection is attached here with. For sterility testing we are following the USP monograph <71>. Submitted Specifications already have specs of sterility and Endotoxin
3.2. P.5.2	• Detailed analytical procedures used for testing the drug product shall be provided	Submitted
3.2. P.5.3	• Assay limits proposed in 3.2.P.5.1 are 90-120%, whereas various parameters of	Typographic mistake.

	Analytical method validation have been performed with limit of90.0% - 110%. • Accuracy parameter has not been performed for concentration range below 100%.	In Linearity and range we had checked the sample even on 50% concentration, which is below 100%, and this gives a linear result. In recent validation methods we had incorporated checking at low concentration for accuracy and recovery below 100%, (i.e 80%), and also at 120%. Revised/Current Method validation is submitted.
3.2. P.5.4	The copies of complete analysis reports of stability batches shall be provided.	Submitted.
3.2. P.5.6	The section declares that "Product is pharmacopoeial". Evidence of monograph shall be submitted for the claimed Pharmacopoeial status of the product.	--
3.2.P.8.3	• Submitted GMP certificate is of other drug substance manufacturer than that declared in section 1.6.5 & 3.2.S.2. • Submitted commercial invoice is of date subsequent to the date of manufacturing of stability batches. • Submitted commercial invoice is from other drug substance manufacturer than that declared in section 1.6.5 & 3.2.S.2. • Submitted COA of stability batches at all time points of stability studies does not include performance of tests of "Uniformity Of Dosage Units", • Submitted Summary sheets of batch #1218408 & 1218409 declare the use of API lot# CLC0420149 for the manufacturing of said batches, but as per submitted commercial invoice the manufacturing date of the said API Lot# CLC0420149 is October 2020, which is subsequent to the date of manufacturing of stability batch#1218408 & 1218409.	API lot No: CLC0417053 is used for all of three stability batches.

Decision: Regsitration Board deferred the case for following:

- **Documents attested by AD DRAP I&E, confirming import of relevant batch# of drug substance used in the manufacturing of drug product stability batches.**
- **Drug product manufacturing and analytical record of recent commercial batch manufactured by M/s Vision Pharmaceuticals.**
- **Registration status of the "Vitamin D3 injection" in name of M/s Vision pahrmaceuticals.**

1386.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Rogen Pharmaceuticals Plot No 30, S-4, national industrial zone, Rawat, Islamabad, Islamabad Capital, Territory**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot No 204-205, Industrial Triangle kahuta road Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No 29540 dated 29-10-2021
	Details of fee submitted	PKR 50,000/-: dated 16/04/2020 (#2031972) PKR 25,000/-: dated 14/10/2021 (#41819350183)
	The proposed proprietary name / brand name	**Mecorol 500mcg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Mecobalamin …… 500mcg
	Pharmaceutical form of applied drug	Red color injectable solution filled in amber glass ampoule.
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Reference to Finished product specifications	Global Specification's
	Proposed Pack size	10x 1ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Methycobal by M/s Eisai Co., Ltd. (Japan), PMDA Approved.
	For generic drugs (me-too status)	Biocobal Injection 500mcg by Surge Laboratories, Reg No: 033385
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-01-2024.
	Name and address of API manufacturer.	Hebei Yuxing Bio-Engineering Co. Ltd High-tech Development Zone, Ningjin County China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: 7805016001, 7805016002 & 7805016001
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Methycobal Injection by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP is not available.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Hebei Yuxing Bio-Engineering Co. Ltd High-tech Development Zone, Ningjin County China		
API Lot No.	M190522		
Description of Pack (Container closure system)	2 Alu-PVC blisters of 5 amber glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	19F015	19G352	19H018
Batch Size	90 Liters	90 Liters	90 Liters
Manufacturing Date	05-2019	07-2019	08-2019
Date of Initiation	03-07-2019	13-11-2019	18-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: The HPLC software is 21 CFR compliant. The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted valid GMP Certificate No: HE2019-142 by National Medical Products Administration China, valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of ADC (I&E) granted by DRAP dated on 09/07/2019, diary No: 1055.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks of Evaluator:

Sr.#	Observations	Firm's response
3.2.S.5	COA of submitted working standard declares validity date as 02-09-2018, whereas drug substance analysis has been performed subsequent to this date, by M/s Global	Coa of an old working standard was submitted mistakenly. COA of working standard actually use din analysis is submitted now.
3.2. P.1	Describe functional role of each excipient used in formulation	Firm has submitted functional role of each excipient used in the formulation , wherein "Benzyl alcohol" has been declared as preservative.
3.2. P.2.2.2	The justification statement "Overage is added to adjust potency", shall be elaborated.	To compnensate the machine variation and to overcome weigt losses in manufacturing process, overage was added.
3.2.P.5.1	• Literature of the innovator product approved by PMDA of japan declares the specifications for pH as 5.3-7.3, whereas firm has proposed pH range of 5.0-7.0. Justification shall be submitted for this variation. • Submitted specification does not include test for "Antimicrobial effectiveness", as recommended by USP general chapter <51>. Justify this disparity since proposed formulation contains "Benzyl Alcohol" as an antimicrobial agent. • Justify the unconventional limits of 90-125% for Assay test.	• As literature of innovator product was not available at the time of product development, pH of innovator product was determined by pH meter and set the pH of our product close to innovator actual pH. Stability studies are around 6.6, which is wel within th elimits of Innovator given in literature. Limit of ph is now changed from 5.0 -7.0 to 5.3 – 7.3 in specifications. • Test for antimicrobial effectiveness is recommended for multi-dose sterile products to check the effectiveness of anti-microbial agent after opening of injection and storage for second dose, our injection is single dose solution. • In drug product specifcations i.e., 90-125% is a typographical mistake. Correct Assay limits are 90-150%.
3.2.P.5.2	• Justification shall be submitted for performance of Assay analysis by "UV spectrophotometric method", whereas the JP monograph of mecobalamin has applied HPLC method. • Different Assay limit between COA (90-150%) and 5.1 (90-125%) •	• JP does not contain mecobalamin injection monograph. We have validated metghod on UV spectrophotometry and performed testing. As the product is developed according to in-house specifications so initially UV method was adopted for testing of drug product. The method was applied for stability studies and later on method was changed to HPLC and stability studies of other batches were carried according to HPLC method. • Firm has not submitted any data as per HPLC method.
3.2.P.5.4	Submitted batch analysis COA specify different Assay limits i.e., 90-150% than those declared in drug product specifications i.e., 90-125% submitted in section 3.2.P.5.1 • No batch size mention on COA • Two batches have Assay results above 125% which is against specifications submitted in section 3.2.P.5.1	• In drug product specifications 90-125% is a typographica;l mistake. Correct Assay limits are 90 -150%. • Batch size of 90.0 ltrs is mentioned on stability data and summary sheets of each batch. • Assay limits are 90-15% as mentioned in stability summary sheets and COAs.
3.2.P.5.6	This section declares details for Ketorolac injection.	It is a typographical mistake.

	3.2.P.8	• Different results for Assay test at initial time point have been reported in stability summary sheet of batch# 19F015 than those declared in COA submitted in section 3.2.P.5.4. • Significant change i.e., more than 5% in Assay results of accelerated stability studies for batch # 19H018 & 19G352 have been reported. • Submitted invoice is subsequent to the manufacturing date of batch# 19F015 • Submitted BMR does not declare the actual quantity dispensed for formulation of batches. • Justification shall be submitted for performance of Assay analysis by "UV spectrophotometric method", whereas the JP monograph of mecobalamin has applied HPLC method.	• It is a typographical mistake, results mentioned in stability summary sheets is correct. • 19H018 contain significant change at 6th month assay and test has been performed as per long term conditions i.e., 30°C ± 2°C / 65% ± 5%RH that covers the additional requirement i..e, 30°C ± 2°C / 60% ± 5%RH as per WHO guidelines. Result salso found within the specified limits i.e., 90-150%. • Firm has submitted copy of License to import fro 5Kg Mecobalamin batch# M190522 issued by AD I&E, Islamabad, dated 09-07-2019. • Firm has submitted copy of manufacturing orders for stability batches wherein excess quantity of 28% for Mecobalamin has been declared. • JP does not contain mecobalamin injection monograph. We have validated metghod on UV spectrophotometry and performed testing. As the product is developed according to in-house specifications so initially UV method was adopted for testing of drug product. The method was applied for stability studies and later on method was changed to HPLC and stability studies of other batches were carried according to HPLC method.

Decision: Deferred for scientific justification of:

- **Using excess quantity of 28% of drug substance in the formulation of submitted drug product stability batches.**
- **Use of "Benzyl alcohol" as preservative since applied formulation is single dose injection.**
- **Performance of Assay analysis during drug product stability studies by "UV spectrophotometric method", whereas the JP monograph of Mecobalamin has applied HPLC method.**

1387.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Rogen Pharmaceuticals Plot No 30, S-4, national industrial zone, Rawat, Islamabad, Islamabad Capital, Territory**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd Plot No 204-205, Industrial Triangle kahuta road Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 28731 dated 20-10-2021
	Details of fee submitted	Rs.25,000/- dated 14-10-2021 & Rs.50,000/- dated 07-05-2020

	The proposed proprietary name / brand name	**Keto-R 30mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Ketorolac Tromethamine ……. 30mg
	Pharmaceutical form of applied drug	Red color injectable solution filled in amber glass ampoule.
	Pharmacotherapeutic Group of (API)	Anti-inflammatory agent, non-steroid
	Reference to Finished product specifications	USP
	Proposed Pack size	1ml×5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ketorolac Tromethamine injection 30mg/ml by M/s Peckforton Pharmaceuticals Limited Crewe Hall, Crewe, Cheshire, CW1 6UL, United Kingdom, MHRA Approved.
	For generic drugs (me-too status)	Toradol Injection 30mg/ml by M/s Barrett Hodgson Pakistan (Pvt.) Ltd. Reg. No. 015000
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-01-2024.
	Name and address of API manufacturer.	M/s Saurav Chemicals Ltd., Unit-III, Village Bhagwanpura, barwala Road, Dera basi, District Ajitgarh (Mohali),Punjab, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, t, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Toradol 30mg/ml Injection.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Saurav Chemicals Ltd., Unit-III, Village Bhagwanpura, barwala Road, Dera basi, District Ajitgarh (Mohali), Punjab, India.		
API Lot No.	KTM180018		
Description of Pack (Container closure system)	Alu-PVC blisters of glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	19C032	19A027	19D011
Batch Size	90 Liters	90 Liters	90 Liters
Manufacturing Date	03-2019	01-2019	04-2019
Date of Initiation	03-07-2019	13-11-2019	18-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: • The HPLC software is 21 CFR compliant. • The firm has provided data loggers with stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP Certificate No: 3124 from Food & Drug Administration, Punjab valid till 24-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of ADC (I&E) granted by DRAP dated on 09/07/2019, diary No: 1055.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks of Evaluator:

Sr.#	Observations	Firm's response
1.3.8-1.5.7	Relevant information has not been submitted	
2.3.R.1.1	Manufacturing process flow chart submitted in the batch manufacturing record declare the product as terminally sterilized via Autoclave, whereas no such step is mentioned in the executed batch manufacturing record. Clarification shall be submitted whether applied product is terminally sterilized or otherwise.	
3.2.S.5	COA of submitted working standard declares validity date as 29-05-2016, whereas drug substance analysis has been performed subsequent to this date, by M/s Global.	
3.2. P.1	Justify the proposed quantity of 30.9mg/ml of Ketorolac tromethamine, declared in composition table against the label claim of 30mg/ml.	
3.2.P.8	• Submit following: i. Documents for the procurement of API with approval from DRAP (in case of import). ii. Analytical record for complete stability studies including chromatograms, raw data sheets etc..	

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

1388.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ahad International Pharmaceuticals Ltd Dera Ismail Khan**
	Name, address of Manufacturing site.	M/s Ahad International Pharmaceuticals Ltd, 13 KM Gomal University Multan Road Dera Ismail Khan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 24365 dated 03-09-2021
	Details of fee submitted	PKR 30,000/-: vide deposit slip# 4953647152

	The proposed proprietary name / brand name	**Parasafe Infusion 1gm/100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml infusion contains: Paracetamol ……. 1gm
	Pharmaceutical form of applied drug	Solution for infusion
	Pharmacotherapeutic Group of (API)	Analgesic and Antipyretic
	Reference to Finished product specifications	In house specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol 10mg/ml solution for infusion (One 100ml vial contains 1000mg Acetaminophen) of M/s Accord-UK Ltd approved by MHRA of UK
	For generic drugs (me-too status)	Provas Infusion 1Gm/100ml by Sami Pharma
	GMP status of the Finished product manufacturer	Panel inspection report dated 09-07-2020 concludes satisfactory level of cGMP compliance.
	Evidence of manufacturing facility	Copy of panel inspection report dated 09-07-2020 has been submitted wherein availability of "Sterile Vial Infusion" & "Ampoule" section has been mentioned.
	Name and address of API manufacturer.	M/s Citi Pharma (Pvt) Ltd, 3KM Head Baloki Road Phool Nagar District Qasur
	Module-II (Quality3. Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Acetaminophen is present in USP and BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence	Pharmaceutical Equivalence have been established against the Provas infusion 1Gm/100ml by Sami Pharma.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	M/s Citi Pharma (Pvt) Ltd, 3KM Head Baloki Road Phool Nagar District Qasur		
API Lot No.	PGP20-423, PARA/AWAS-001/20-001		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 25˚C ± 2˚C / 60% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	001	002	003
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	15-09-2020	16-09-2020	17-09-2020
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.3.1	The said section declares M/s Hebei Jiheng Pharmaceutical Co. Ltd as producer of Acetaminophen instead of M/s Citi Pharma.	According to invoice Neon chemical is our indenter which deals both companies. Now we are performing all the procedure according to Hebei Jiheng Pharma.
3.2.S.4.2	Analytical procedure submitted by Drug substance manufacturer is as per USP monograph, whereas Drug product manufacturer has submitted	Drug substance manufacturer complies both BP & USP specifications. Now we adopt analytical procedure according to USP specification.

	analytical procedure as per BP monograph. Justification shall be submitted for this variation.	
3.2.S.4.3	• Clarification shall be submitted that whether submitted analytical method verification studies have been performed by M/s Citi Pharma or M/s Ahad International. • Clarification shall be submitted that whether submitted analytical method verification studies have been performed as per USP or BP monograph.	• Analytical method verification studies have been performed M/s Ahad International. • Performed according ot USP monograph.
3.2.S.4.4	• COA of Paracetamol submitted from M/s CITI Pharma declares it as "Analytical Working Standard", whereas results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer shall be submitted. • Submitted COA form M/s Citi Pharma & M/s Ahad International does not include test of sterility. Clarification shall be submitted in this regard, since the drug substance is to be used in the formulation of a sterile product.	• Firim has submitted COA of drug substance from M/s Hebei Jiheng Pharmaceutical Co. Ltd. China for batch# COS012012049 which also includes sterility test.
3.2.S.4.5	The said section declares that the specifications adopted are as per the monograph specified in USP while in section 3.2.S.4.2 analytical procedure as per BP monograph has been submitted.	Drug substance manufacturer complies both BP & USP specifications. Now we adopt analytical procedure according to USP specification.
3.2.P.3.5	Submitted process validation protocol mentions the strength as 1000mg/10ml whereas applied strength is 1000mg/100ml.	It is typographic mistake while the original strength is 1000mg/100ml.
3.2.P.5.1	Justification shall be submitted for the proposed pH range of 4.0 -7.0 for the drug product since the available literature of the reference product declares different pH range than that proposed by the applicant.	Actual pH range 5 – 7 for drug product according to USP specifications.
3.2.P.5.3	Performance of Linearity parameter shall be submitted in Analytical method validation studies.	Submitted.
3.2.P.5.4	The copies of complete analysis reports of all three trial batches shall be provided. Submitted analytical report of Trial-01 does not include test of Sterility & Endotoxin.	Firm has submitted copies of batch analysis reports fo all three stability bayches including results for sterility testing and endotoxin.
3.2.P.8	• Submitted invoice from M/s Neon Chemicals declare quantity of Paracetamol as of	• Firm has submitted copy of letter from M/s Neon Chemicals, declaring submission of drug sample of

	50gm. Justification shall be submitted for manufacturing of three trial batches of 400vials each with 50gm of API. • Submitted stability summary sheets & reports declare condition of real time stability studies as 25˚C ± 2˚C / 60% ± 5%RH which is not as per Zone IVa. • Submitted analytical record shows that Assay calculations for all three stability batches at each time point of both accelerated & long-term stability studies have been performed by applying same value of Standard peak area. Justification shall be submitted in this regard. • Record of data logger of stability chambers shall be submitted. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	2Kg from M/s Hebei Jiheng Pharmaceutical Co., Ltd., China to M/s Ahad International. • No document attested by AD I&E DRAP has been submitted in this regard. • Firm has submitted revised stability summary sheets m conditions as per Zone Iva. • Firm has submitted revised analytical record along with chromatograms. • Record of digital data logger has been submitted. • GMP certificate eof the drug substance manufacturer has not been submitted.
Decision: Deferred for clarification regarding manufacturer of drug substance along with documents confirming procurement of drug substance with approval of DRAP I&E office.		

1389.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals Limited. Plot No. 65, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, Punjab, Pakistan
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30772 dated 10-11-2021
	Details of fee submitted	Rs.75,000/- dated 29-10-2021
	The proposed proprietary name / brand name	**Maxflow-S 0.4mg/6mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer modified release tablet contains: Solifenacin succinate…….6mg (Corresponding to 4.5mg of Solifenacin base) Tamsulosin hydrochloride…….0.4mg (Corresponding to 0.37mg of Tamsulosin base)
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Antimuscarinics/Alpha-blockers

	Reference to Finished product specifications	Innovator
	Proposed Pack size	5's, 10's, 14's, 20's, 28's, 30's, 50's and 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Vesomni Tablet by M/s Astellas Pharma Ltd., EMA Approved.
	For generic drugs (me-too status)	Tamsolin -S by M/s Getz Pharma
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate dated 04-01-2022.
	Name and address of API manufacturer.	M/s Alphamed Formulations Pvt. Ltd Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Solifenacin Succinate & Tamsulosin HCl is not present in Pharmacopoeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Tamsulosin HCL Batches: (8000173-039(A), 8000173-045(A), 8000173-046(A)) Solifenacin Succinate Batches: (8000173-039(B), 8000173-045(B), 8000173-046(B))
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator Vesomni Tablet by M/s Astellas Pharma Ltd, UK by performing quality tests

		(Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Vesomni Tablet by M/s Astellas Pharma Ltd, UK in Acid media & Phosphate Buffer. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Alphamed Formulations Pvt. Ltd. Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India		
API Lot No.	Tamsulosin HCl: 8000173-041(A) Solifenacin Succinate: 8000173-041(B)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T5-01	T5-02	T5-03
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	09-2017	09-2017	09-2017
Date of Initiation	10-10-2017	10-10-2017	10-10-2017
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 30/08/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of Invoice, Diary No. 2142 dated 04/08/2017 is submitted wherein the permission to import API Tamsulosin HCl and Solifenacin Succinate is granted. • Invoice No. 034/2017-18 attested by AD I&E dated 04-08-2017.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator(Ammar):

Subsequently firm has submitted stability studies data of 2 commercial batches along with full fee of Rs. 75,000/- vide deposit slip# 986205168101. Details of the commercial batches data is as under:

Manufacturer of API	M/s Alphamed Formulations Pvt. Ltd. Sy.No.225, Sampanbole Village Shamirpet Mandel, Medchal-Malkajigiri District, Telangana-500 078, India		
API Lot No.	Tamsulosin HCl: AT0018-002 Solifenacin Succinate: AT0019-003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21L133	21M294	--
Batch Size	110,000 tab	110,000 tab	--
Manufacturing Date	11-2021	12-2021	--
Date of Initiation	29-12-2021	20-01-2022	--
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate valid till 30/08/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Pharmaceutical equivalence and CDP Studies data in three dissolution mediums of pH 1.2, 4.5 & 6.8 has been submitted against the Tamsolin-S tablet pf M/s Getz Pharma		

Section#	Observations	Firm's response
3.2.S.4 (Tamsulosin HCl)	• Submitted drug substance specifications of Tamsulosine granules does not include test of dissolution hence it's not evident that the Tamsulosine granules are modified release or otherwise. Justification shall be submitted in this regard. • Submitted COA from both drug substance and drug product manufacturer does not declare	• With reference to the control of drug substance, API manufacturer has tested the dissolution against the RLD Vesomni, but did not include the test in release specifications. Moreover, FPP Manufacturer has included the Dissolution Testing of Tamsulosin Granules at finished product stage, that shows the granules release is modified. • Dissolution testing is not included in the release specification. However, modified

	the Tamsulosine granules as "modified release". • Justification shall be submitted for using Tamsulosine granules 0.178% w/w% for drug product formulation without establishing its dissolution profile.	release of tamsulosin granules is declared in the label claim of the Finished Product. • Dissolution profile of the granules established at FPP stage as evident from the Product testing Method and CDP.
3.2.P.1	• Submitted label claim does not elaborate the immediate release & modified release layer of the dosage form.	Label claim of the tablet is as follow: Each bilayer modified release tablet contains: Solifenacin succinate… 6mg (Corresponding to 4.5mg of Solifenacin base) (Immediate release layer) Tamsulosin hydrochloride….0.4mg (Corresponding to 0.37mg of Tamsulosin base) (Modified release layer)
3.2.P.2.2.1	• Justification shall be submitted for performing CDP studies till 12 hours' time point only, whereas the drug product specifications mention the last time point as of 16hrs.	For Tamsulosin in CDP, release NLT 80% achieved in 12hours therefore next time point was not included in consideration.
3.2.P.5	• Justification shall be submitted for applying speed of 100rpm with USP Apparatus II in the dissolution test with reference to the provisions of USP general chapter <1092>.	According to USP General Chapter <1092>, Please consider the following, *"100 rpm may be used with Apparatus 2, especially for extended-release products. Decreasing or increasing the apparatus rotation speed may be justified if to achieve an in vitro–in vivo correlation (IVIVC) the resulting profiles better reflect in vivo performance, or if the method results in better discrimination without adversely affecting method variability."*
3.2.P.8.3	• Documents confirming import of drug substance used for formulation of stability batches, attested by DRAP, shall be submitted.	Copy of letter issued by AD I& E DRAP Islamabad, dated 28-10-2021, permitting import of Solifenacin 6% granules (25Kg) & Tamsulosin HCl 0.178% granules (50 Kg)
	• Submitted BMRs does not reflect the dispensing of Magnesium stearate, whereas the composition submitted in section 3.2.P.1 includes magnesium stearate. • Dispensed quantity of Tamsulosine HCl granules & Solifenacin granules, shall be justified against the potency determined during drug substance analysis.	• Mg. stearate in Section 3.2.P.1 is approximately 2% of the formulation which is used to increase the flow properties of granules only if required and that would be of Pharmacopeial Grade (BP), if used. Therefore, submitted BMR does not includes the Mg. Stearate. • Potency determined during the Analysis of both the drug substance is more than 100%, that's why Potency is considered equivalent to 100% while dispensing of Drug substance.

Decision: Deferred for following:

- **Justification for claiming "Tamsulosine HCl granules" as modified relase since no such declaration has been maned in drug substance specifications and COA.**
- **Scientific justification from drug substance emanufcaturer for not including test of "Dissolution" in the specifications of "Tamsulocin HCl granules" for establishing the modified release profile.**
- **Scientific justification from drug product manufacturer for not establishing dissolution profile of "Tamsulosine HCl granules" vide performance of dissolution test before using them as in the drug product formulation.**
- **Capacity assessment of manufacturing and testing facility of M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**

1390.	**Name, address of Applicant / Marketing Authorization Holder**	**"M/s** Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan."
	Name, address of Manufacturing site.	"M/s Ray Pharma Pvt. Ltd, S-58, S.I.T.E Karachi, Pakistan."
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 24845 dated 08-09-2021
	Details of fee submitted	Rs.30,000/- dated 04-06-2021
	The proposed proprietary name / brand name	**WFI Injection 5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Sterile Water for Injection……5ml
	Pharmaceutical form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Solvent
	Reference to Finished product specifications	USP
	Proposed Pack size	1's (5ml) x 100 ampoules per pack
	Proposed unit price	Rs. 5.75 Per Ampoule
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Water for Injection of M/s Martin Dow
	GMP status	GMP certificate issued on basis of inspection conducted on 05-07-2022
	Name and address of API manufacturer.	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , analytical procedures, batch analysis and justification of specification, reference standard, and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	NA
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, , control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	Pharmaceutical Equivalence studies have been performed against the WFI of M/s Martin Dow
	Analytical method validation/verification of product	N/A
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions

STABILITY STUDY DATA

Manufacturer of API	NA		
API Lot No.	NA		
Description of Pack (Container closure system)	Type I Glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,3,6 (Months) Real Time: 0,1,3, 6 (Months)		
Batch No	PD021	PD022	PD023
Batch Size	400 ampoules	2000 ampoules	2000 ampoules
Manufacturing Date	10-2020	10-2020	10-2020

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any).	
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Not applicable
3.	Documents confirming import of API etc.	Not applicable
4.	Data of stability batches will be supported by attested respective documents like	Yes

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

REMARKS OF EVALUATOR

Observations	**Firm's response**
3.2.S.4 You have submitted finished product specifications, COA, analytical method etc. instead of providing drug substance information.	Firm has submitted specifications and analytical method for drug substance.
Justify why the test for nitrates, sulphates, Aluminium and ammonium are not performed during stability studies.	We follow the USP specifications and as per USP 43 official monograp/ water 4653 we performed (appearance, pH, Conductivity, Total Orgainc Carbon, Bacterial Endotoxin tests) thereof tests of nitrates, sulphates, aluminum and ammonium are not mentioned in USP specifications.

Decision: Approved.

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

1391.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh**
	Name, address of Manufacturing site.	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on 13-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32576 dated 30-11-2021
	Details of fee submitted	Rs.50,000/- dated 29-03-2021
	The proposed proprietary name / brand name	**Parmol 1000mg/100ml Infusion**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Paracetamol ……. 1000mg
	Pharmaceutical form of applied drug	Parenteral (Injectable)
	Pharmacotherapeutic Group of (API)	Analgesic/Antipyretic
	Reference to Finished product specifications	Manufacturer's Spec
	Proposed Pack size	1's x 100ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Falgan infusion of M/s Bosch
	Name and address of API manufacturer.	ANHUI BBCA LIKANG PHARMACEUTICAL CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is BOFALGAN 1g/100ml Solution for infusion by **BOSH PHARMACEUTICALS (PVT) LTD** by performing quality tests (Identification, Assay, sterility & volume variation N/A
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.
STABILITY STUDY DATA		

Manufacturer of APIs	Anhui BBCA Likang Pharmaceutical CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China		
API Lot No.	202002047A		
Description of Pack (Container closure system)	Type III 100 ml glass vial pack in unit carton is used as primary packaging (1 x1 vial)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PI-001	PI-001	PI-001
Batch Size	3500 Vials	3500 Vials	3500 Vials
Manufacturing Date	08-2021	08-2021	08-2021

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

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

Remarks of Evaluator:

Section	Observation	Firm's response
1.6.5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.P.8.3	• Documents confirming procurement of drug substance shall be submitted. • Complete batch manufacturing record of stability batches shall be submitted.	• Copy of commercial invoice no. 20NVT-090 attestedby AD DRAP I&E Karachi dated 27-03-2020 forimport of 1000 Kg of Paracteamol in name of M/s Inventor.

Decision: Deferred for submission of following:

- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.**
- **Complete batch manufacturing record of stability batches.**

1392.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Standard Drug Company. E-6A, S.I.T.E Hyderabad**
	Name, address of Manufacturing site.	M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on 13-08-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32576 dated 30-11-2021
	Details of fee submitted	Rs.50,000/- dated 29-03-2021
	The proposed proprietary name / brand name	**Strapals 1000mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml vial contains: Paracetamol ……. 1000mg
	Pharmaceutical form of applied drug	Parenteral (Injectable)
	Pharmacotherapeutic Group of (API)	Analgesic/Antipyretic
	Reference to Finished product specifications	Manufacturer's Spec
	Proposed Pack size	1's x 100ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Falgan infusion of M/s Bosch
	Name and address of API manufacturer.	ANHUI BBCA LIKANG PHARMACEUTICAL CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its validation, batch analysis and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is BOFALGAN 1g/100ml Solution for infusion by **BOSH PHARMACEUTICALS (PVT) LTD** by performing quality tests (Identification, Assay, sterility & volume variation N/A
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.

STABILITY STUDY DATA

Manufacturer of APIs	Anhui BBCA Likang Pharmaceutical CO., LTD Address: No 6288 Donghai Road, Bengube city, Anhui province, China		
API Lot No.	202002047A		
Description of Pack (Container closure system)	Type III 100 ml glass vial pack in unit carton is used as primary packaging (1 x1 vial)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PI-001	PI-001	PI-001
Batch Size	3500 Vials	3500 Vials	3500 Vials
Manufacturing Date	08-2021	08-2021	08-2021

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	**Documents To Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.

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

Remarks of Evaluator:

Section	Observation	Firm's response
1.6.5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.P.8.3	• Documents confirming procurement of drug substance shall be submitted. • Compete batch manufacturing record of stability batches shall be submitted.	Copy of commercial invoice no. 20NVT-090 attestedby AD DRAP I&E Karachi dated 27-03-2020 forimport of 1000 Kg of Paracteamol in name of M/s Inventor.

Decision: Deferred for submission of following:

- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.**
- **Complete batch manufacturing record of stability batches.**

1393.	Name, address of Applicant / Marketing Authorization Holder	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpind
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status & Evidence of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Bio-Labs dated 21-05-2019 based on the inspection dated 23-04-2019. The certificate is valid till 22-04-2022. The GMP certificate specifies Lyophilized vial (General) section. Firm has also submitted copy of letter for grant of additional section dated 23-07-2012 specifying Lyophilized vial (General) section.
	Dy. No. and date of submission	Dy.No 27956 dated 11-10-2021
	Details of fee submitted	Rs.75,000/- dated 20-09-2021

	The proposed proprietary name / brand name	**Inviczole 40mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each lyophilized vial contains: Esomeprazole as sodium……..40mg
	Pharmaceutical form of applied drug	Almost white colored lyophilized, hygroscopic powder filled in glass vial.
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	In-house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nexium IV 40mg Injection of M/s AstraZeneca (USFDA approved).
	For generic drugs (me-too status)	Esomine 40mg Injection of M/s Lawari International (Reg # 069703)
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conduct 23-4-2019, valid upto 22-4-2022.
	Name and address of API manufacturer.	M/s. Sterile India Pvt. Ltd. Plot No. 100, Sec-56 Phase - 4, Kundli Sonipat (Haryana) India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. (Batch No. SI/EPZ/0010312, SI/EPZ/0020312 & SI/EPZ/0030312).
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development,

		manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted pharmaceutical equivalence study report of trial formulation (Batch # L-315) with Nexum 40mg injection (Batch # 137P07) of M/s Getz pharma by performing quality tests (Description, water contents, pH, Sterility, assay). CDP- Not applicable
	Analytical method validation/verification of product	Analytical method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Sterile India Pvt. Ltd. Plot No. 100, Sec-56 Phase -4, Kundli Sonipat (Haryana) India		
API Lot No.	SI/EPZ/00061217		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
E-Zole 40mg Injection			
Batch No.	L-315	L-287	L-283
Batch Size	5,000 vials	5,000 vials	5,000 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	26-02-2020	22-02-2020	28-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED WITH STABILITY STUDY		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of M/s. Sterile India Pvt. Ltd. Plot No. 100, Sec-56 Phase -4, Kundli Sonipat (Haryana) India valid upto 21-5-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted attested copy of invoice (invoice# E/161/SIPL/19-20)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has not submitted audit trail reports on product testing.

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

- Submit differential fee for the registration of applied product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP after 7th May 2021.
- Manufacturer has changed specifications of the drug product without submission of fee.
- The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabadhave already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product in 316th meeting are as follows:

Applicant firm	M/s Gray's Pharmaceuticals. Plot No. 2, Street No. N-3, RCCI Rawat Rawalpindi.
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad
Brand Name	ESOMEP Injection 40mg
Batch No. of drug product	L-315, L-287, L-283
Case No.	787
Registration Board meeting	316th meeting of Registration Board

Decision: Approved.

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

1394.	Name, address of Applicant / Marketing Authorization Holder	Welwrd Pharmaceuticals Plot No.3, Block A, Phase-II Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10,RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. dated 08/10/2021
	Details of fee submitted	PKR 75,000/-: dated 30/09/2021
	The proposed proprietary name / brand name	**Meropenem Injection I.V 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……..500mg (Blended with sodium carbonate)

	Pharmaceutical form of applied drug	Glass vial filled with almost white powder packed in unit carton.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.
	GMP status of the Finished product manufacturer	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MRPS-001/10, MRPS-002/10, MRPS-003/10)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Meronem 500mg injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance and drug product.

STABILITY STUDY DATA				
Manufacturer of API		Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi– District Alwar Rajasthan India.		
API Lot No.		UIMRPS19021		
Description of Pack (Container closure system)		Glass vial		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		MR-001	MR-002	MR-003
Batch Size		350 vials	350 vials	350 vials
Manufacturing Date		01-2020	01-2020	01-2020
Date of Initiation		07-01-2020	07-01-2020	07-01-2020
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DC/A-1/WHO-GMP/2020/1961) issued by Drugs control organization, Governmnet of Rajasthan dated 09-12-2020. The certificate is valid till 26-02-2022.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of meropenem 3Kg from M/s Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India issued by AD (I&E) DRAP field office. The license was issued on 02-01-2020. • Firm has submitted copy of commercial invoice dated 02-01-2020 specifying import of 3Kg meropenem. The invoice is signed by AD (I&E) DRAP.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for only single day 01-07-2020.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.		
Remarks of Evaluator:				
1395.	Name, address of Applicant / Marketing Authorization Holder	Welwrd Pharmaceuticals Plot No.3, Block A, Phase-II Industrial Estate, Hattar.		

	Name, address of Manufacturing site.	M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10,RCCI Industrial Estate Rawat Islamabad.
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. dated 08/10/2021
	Details of fee submitted	PKR 75,000/-: dated 30/09/2021
	The proposed proprietary name / brand name	**Meropenem Injection I.V 1g**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem (as trihydrate)……..1g (Blended with sodium carbonate)
	Pharmaceutical form of applied drug	Glass vial filled with almost white powder packed in unit carton.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.
	GMP status of the Finished product manufacturer	Firm has been granted new DML by way of formulation dated 06-11-2019.
	Name and address of API manufacturer.	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MRPS-001/10, MRPS-002/10, MRPS-003/10)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Meronem 1g injection.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi– District Alwar Rajasthan India.		
API Lot No.	UIMRPS19021		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MR-004	MR-005	MR-006
Batch Size	350 vials	350 vials	350 vials
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	07-01-2020	07-01-2020	07-01-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DC/A-1/WHO-GMP/2020/1961) issued by Drugs control organization, Governmnet of Rajasthan dated 09-12-2020. The certificate is valid till 26-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 "License to import drugs for clinical trial, examination, test or analysis" for import of meropenem 3Kg from M/s Rajasthan Antibiotics Ltd. Plot No. 619 & 630 RIICO Industrial Area Bhiwadi – District Alwar Rajasthan India issued by AD (I&E) DRAP field office. The license was issued on 02-01-2020. • Firm has submitted copy of commercial invoice dated 02-01-2020 specifying import of 3Kg

		meropenem. The invoice is signed by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for only single day 01-07-2020.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Remarks of Evaluator: The applied formulation has already been approved for M/s Bio-next Pharma on basis of evaluation of Form 5F application in 296th meeting held on 8th, 9th & 10th September 2020.		
Decision: Registration Board approved the applications of Meropenem Injection I.V 500mg & Meropenem Injection I.V 1gm. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection"** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Bio-Next Pharmaceuticals wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.**		

b. Deferred cases

1396	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited, 7-Jail Road, Quetta**	
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited, F-126, S. I. T. E., Karachi, Pakistan	
	Status of the applicant	☐Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy.No 25930 dated 17/09/2021	
	Details of fee submitted	PKR 50,000/-: PKR 25,000/-:	dated 04/05/2020 dated 30/06/2021

	The proposed proprietary name / brand name	ADVITA 20,000 IU CAPSULES
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Soft gel Capsule contains: Cholecalciferol…...20,000 IU
	Pharmaceutical form of applied drug	Clear light-yellow oily liquid
	Pharmacotherapeutic Group of (API)	Vitamin D analogs
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Fultium 20,0000 IU Capsule by M/s Internis Pharmaceuticals Limited, MHRA Approved.
	For generic drugs (me-too status)	
	GMP status of the Finished product manufacturer	Certificate No: F.14-1/DRAP/GMP/MDM-2022 issued on 03rd Feb 2022 Soft Gelatin Capsule (General) Dispensing, Mixing, Drying, Granulation, Compression, Coating, Blistering & Packaging.
	Name and address of API manufacturer.	M/s DSM Nutritional Product, France
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25°C ± 2°C / 60% RH ± 5% RH for 24 months Accelerated: 30°C ± 2°C / 65% RH ± 5% RH for 6 months

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that **Fultium 20,0000 IU Capsule by M/s Internis Pharmaceuticals Limited**. Since Vitamin D3 capsules are Fat soluble in nature so the dissolution in not recommended by any Pharmacopoeia & FDA dissolution guideline.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s DSM Nutritional Product, France		
API Lot No.	11F01901004		
Description of Pack (Container closure system)	Aluminum foil with PVC/PVDC blister (2×7's)		
Stability Storage Condition	Real time: 25°C ± 2°C / 60% ± 5%RH Accelerated: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-007/20	TR-008/20	TR-009/20
Batch Size	10000 capsule	10000 capsule	10000 capsule
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	Acidex 60mg Capsule Dexlansoprazole was approved in 312th Registration Board meeting. 1) Compliance Record of HPLC software 21CFR & audit trail reports on product testing were present
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No 18MPP077HFR02 issued by EUDRA . Period of validity is extended to 26.09.2023 in case of cholecalciferol .

	Documents for the procurement of API with approval from DRAP (in case of import).	**M/s DSM Nutritional Product, France** ADC Invoice No: 2831239200, 29-08-2019
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of batches along with chromatograms, raw data sheets, COA and summary data sheets
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted compliance record of HPLC software 21 CFR and copies of audit trail on testing of drug product.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

Decision of 320th meeting: Deferred for following points:

- Clarification of conditions of stability studies of drug substance and drug product.
- Justification why comparative dissolution profile studies are not performed against the innovator drug product.

Firm's response:

- Cholecalciferol is sensitive & not stable when exposed to high temperature condtion so in the light of above condition stability performed at 25ºC +2ºC/60% RH +5%RH. SmPc of innovator product "Fultium-D3 20,000IU capsules" clearly instructed to store the product below 25ºC.

- As Choleclaciferol is present in USP and its nature is fat soluble. Therefore, its dissolution is not recommended in any Pharmacopoeia as well as FDA dissolution guideline. While complete comparative analysis & Pharmaceutical equivalence with innovator has already been submitted with initial dossier.

Decision: Deferred for following:

- **Scientific justification for performing drug product stability studies on storage conditons different from that required by ICH/WHO guidelines for Zone IVA.**
- **Submission of reference from pharmacopoeia/ innovator drug product literature regarding non-performance of dissolution test for applied formulation.**

1397.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited., Plot 37-A, Sundar Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited., Plot 37-A, Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33576 Dated 10-12-2021
	Details of fee submitted	PKR 30,000/-: Dated 29-11-2021
	The proposed proprietary name / brand name	Citromark 2.5 mg / 5ml oral solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 mL oral solution contains: Levocetirizine dihydrochloride ……..... 2.5 mg
	Pharmaceutical form of applied drug	Oral solution
	Pharmacotherapeutic Group of API	Anti-histamine
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	60 mL
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XYZAL 0.5 mg / ml oral solution by M/s UCB Pharma (USFDA Approved)
	For generic drugs (me-too status)	T-Day 0.5 mg / mL oral solution by M/s GSK Consumer Healthcare Reg. No. 083990
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019 Oral liquid Syrup Section
	Name and address of API manufacturer.	M/s Metrochem API Private Limited., Factory: Unit-I, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla Hyderabad-500 055, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levocetirizine Dihydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and

		specific optical rotation, heavy metals and enantiomeric purity by HPLC, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (LCZ/A/200801001, LCZ/A/200801002, LCZ/A/200801003)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **T-day 0.5 mg/mL oral solution** by GSK consumer healthcare by performing quality tests (Identification, Assay, and of uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Metrochem API Private Limited., Factory: Unit-I, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla Hyderabad-500 055		
API Lot No.	LUVPC21027		
Description of Pack (Container closure system)	Amber color pet bottle packed in unit carton (1×60 mL)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	100 bottles	100 bottles	100 bottles
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	13-05-2021	13-05-2021	13-05-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 1296/DD/DCA/VSP/2020 issued by Deputy Director & Certifying Authority drugs control administration Visakhapatnam Region India valid up to 28-09-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levocetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches including raw data sheets, COAs, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Sr. No.	Observations	Response by the firm
1.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of standard and sample preparation methods alongwith chromatograms in different parameters were not provided.*
2.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided	Applicant batch No: T-02 **Comparator product:** T-day 2.5mg / 5ml oral solution of M/s GSK consumer healthcare Batch No: HH11L
3.	Discussion of microbiological attributes of the Drug Product (e.g. preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	The firm has not submitted preservative effectiveness studies as recommended by pharmacopoeia.
4.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	The firm has submitted analytical method verification reports of drug product. *However, details of standard and sample preparation methods alongwith chromatogram in different parameters were not provided.*
5.	The submitted copy of GMP certificate of API manufacturer is expired on 28-09-2021. Updated copy of GMP certificate shall be submitted.	The firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Telangana India valid up to 20-05-2023.
6.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levocetirizine Dihydrochloride for the purpose of test/analysis

		and stability studies is granted. However, invoice is not cleared by AD (I&E) DRAP of field office.
7.	The submitted chromatograms do not differentiate between real time or accelerated stability studies of prepared batches.	Not submitted
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that *audit trail is maintained manually.*

Decision of 317th meeting: Deferred for submission of following:

- Analytical method verification report of drug substance performed by drug product manufacturer as
- per requirement of section 3.2.S.4.3 of Form-5F.
- Performance of pharmaceutical equivalence and CDP studies with innovator/reference product.
- Preservative effectiveness studies as recommended by Pharmacopoeia.
- HPLC chromatograms of all time points of real time and accelerated stability studies.
- Analytical method verification reports for testing of drug product as per requirements of section 3.2.P.5.3 of Form-5F.

Firm's response: Firm has submitted following:

- Analytical method verification studies for drug substance performed by M/s Himark.
- Pharmaceutical equivalence studies against the T-Day syrup.
- Preservative efficacy studies for all three stability batches.
- Analytical method verification report for drug product
- HPLC chromatograms of the stability studies.

Decision of 323rd meeting: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**

1398.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019. Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission	Dy. No. 33577 Dated: 23-12-2021
	Details of fee submitted	PKR 30,000/-: Dated 29/11/2021
	The proposed proprietary name / brand name	**Fexomark 120mg film coated tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine hydrochloride……120mg
	Pharmaceutical form of applied drug	Whilte colored round shaped film coated tablet, Packed in Alu-Alu Blisters (1 × 10's).
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 × 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telfast 120mg film coated tablet of M/s Aventis Pharma Limited, United Kingdom (MHRA approved).
	For generic drugs (me-too status)	Fexet 120mg film coated tablet of M/s GETZ Pharma
	Name and address of API manufacturer.	M/s VPL Chemicals Pvt. Ltd., Plot # 64, 1st phase, Sompura Industrial Area, Dobbespet, Nelamangala (Taluk), Bangalore Rural – 562 111, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (FE III 1503013, FE III 1503014, FE III 1503015).
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference

		standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted pharmaceutical equivalence against comparator product **Telfast 120 mg tablet** by **Sanofi-Aventis** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage unit). CDP has been performed against the comparator product **Fexet 120 mg Tablet** of **M/s GETZ pharma** in acidic media (pH 1.0-1.2) and pH 4.5 buffer & phosphate buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s VPL Chemicals Pvt. Ltd., Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala (Taluk), Bengaluru Rural-562 111, India.		
API Lot No.	FEX2103012		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	10-05-2021	10-05-2021	10-05-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API / DML / GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. DCD/SPL-1/CR-1207/2020-21 issued by Government of Karnataka, Drugs Control Department India valid up to 05-01-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD (I&E) dated 26/12/2019 wherein the permission to import different APIs including Fexofenadine hydrochloride for the purpose of test/analysis and stability studies is granted. Copy of invoice for the purchase of API has not submitted.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches including raw data sheets, COAs, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Sr. No.	**Observations**	**Response by the firm**
1.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of standard and sample preparation methods alongwith chromatograms of different tested parameters were not provided.*
2.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided	Applicant batch No: T-01 **Comparator product:** T-day 5mg Tablet of M/s Sanofi-Aventis Batch No: AN002
3.	Justify your acceptance criteria for dissolution test as NLT 60% of the labeled amount of Fexofenadine HCl is dissolved in 10 min; NLT 80% of the labeled amount of Fexofenadine HCl is dissolved in 30 min while USP has specified as NLT 60% (Q) of the labeled amount of Fexofenadine HCl dissolved in 10 min; NLT 80% (Q) of the labeled amount of Fexofenadine HCl dissolved in 30 min.	USP defines quantity Q, is the amount of dissolved active ingredient specified in the individual monograph. When we look at a Q value, we are looking at what percent has dissolved at that time. Thus, there is no difference between NLT 60% in 10 min and NLT 60% (Q) in 10 minutes and NLT 80% in 30 min and NLT 80 (Q) in 30 min. *However, USP general chapter of dissolution <711> defines S1 stage of dissolution as each unit is not less than Q + 5% and did not revise dissolution acceptance criteria as per USP.*
4.	Submit acceptance criteria for release and shelf life specifications.	The firm has submitted acceptance criteria for release and shelf life specifications.
5.	Justify dissolution results in the submitted batch analysis since results are not complying USP monograph.	The firm has referred to USP definition of Q, as the amount of dissolved active ingredient specified in individual monograph. *The firm has not provided justification of dissolution results not complying USP monograph.*
6.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	The firm has submitted analytical method verification reports of drug product. *However, details of standard and sample preparation methods alongwith chromatograms of different tested parameters were not provided. The results of repeatability parameter show absorbance values while rest of the parameter gives values in peak area.*
7.	COA of primary / secondary reference standard including source and lot number shall be provided.	The firm has submitted COA of working standard from drug substance manufacturer with lot no. WS-Fex-210209.
8.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levocetirizine

		Dihydrochloride for the purpose of test/analysis and stability studies is granted. However, invoice is not cleared by AD (I&E) DRAP of field office.
9.	The submitted chromatograms do not differentiate between real time or accelerated stability studies time points of different batches.	Not submitted
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that audit trail is maintained manually.
11.	Submit copies of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of batch manufacturing record of stability batches.
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Decision of 317th meeting: Deferred for submission of following:

- Analytical method verification report of drug substance performed by drug product manufacturer as
- per requirement of section 3.2.S.4.3 of Form-5F.
- Performance of pharmaceutical equivalence and CDP studies with innovator/reference product.
- Justify acceptance criteria for dissolution test in the light of USP monograph.
- Justify dissolution results in the submitted batch analysis since results are not complying USP specifications.
- HPLC chromatograms of all time points of real time and accelerated stability studies.
- Analytical method verification reports for testing of drug product as per requirements of section 3.2.P.5.3 of Form-5F.

Firm's response: Firm has submitted following:

- Analytical method verification studies for drug substance performed by M/s Himark.
- Pharmaceutical equivalence & CDP studies in three dissolution mediums against the Telfast tablet.
- Revised dissolution limits as per USP monograph as under:
  - NLT 60(Q) i.e., 65% of the labelled amount of Fexofenadine HCl is dissolved in 10 minutes.
  - NLT 60(Q) i.e., 85% of the labelled amount of Fexofenadine HCl is dissolved in 30 minutes.
- Dissolution test has been repeated in 10minutes our results did not fall in S1 stage. However, in S2 stage our results qualify i.e., no dissolution result is below 60%.
- HPLC chromatograms for stability studies.
- Analytical method verification report for drug product

Decision of 323rd meeting: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**

1399.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited, Plot 37-A, Sunder Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019. Tablet (General & General Antibiotic) section approved.
	Dy. No. and date of submission	Dy. No. 33578 Dated: 23-12-2021
	Details of fee submitted	PKR 30,000/-: Dated 29-11-2021
	The proposed proprietary name / brand name	**Fexomark 180mg film coated tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine hydrochloride……180mg
	Pharmaceutical form of applied drug	Whilte colored round shaped film coated tablet, Packed in Alu-Alu Blisters (1 × 10's)
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1 × 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telfast 180mg film coated tablet of M/s Aventis Pharma Limited, United Kingdome (MHRA approved).
	For generic drugs (me-too status)	Fexet 180mg film coated tablet of M/s GETZ Pharma
	Name and address of API manufacturer.	M/s VPL Chemicals Pvt. Ltd., Plot # 64, 1st phase, Sompura Industrial Area, Dobbespet, Nelamangala (Taluk), Bangalore Rural – 562 111, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months Batches: (FE III 1503013, FE III 1503014, FE III 1503015).
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference

		standard or materials, container closure system and stability.		
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted pharmaceutical equivalence against comparator product **Telfast 180 mg tablet** by **Sanofi-Aventis** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Telfast 180 mg Tablet** by **Sanofi-Aventis** in Acid media (pH 1.0-1.2) and pH 4.5 & phosphate buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.		
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted.		
STABILITY STUDY DATA				
Manufacturer of API		M/s VPL Chemicals Pvt. Ltd., Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala (Taluk), Bengaluru Rural-562 111, India.		
API Lot No.		FEX2103012		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-01	T-02	T-03
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date		05-2021	05-2021	05-2021
Date of Initiation		11-05-2021	11-05-2021	11-05-2021
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API / DML / GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. DCD/SPL-1/CR-1207/2020-21 issued by Government of Karnataka, Drugs Control Department India valid up to 05-01-2025.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD (I&E) dated 26/12/2019 wherein the permission to import different APIs including Fexofenadine hydrochloride for the purpose of test/analysis and stability studies is granted. Copy of invoice for the purchase of API has not submitted.		

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches including raw data sheets, COAs, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Sr. No.	Observations	Response by the firm
1.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of standard and sample preparation methods alongwith chromatograms of different tested parameters were not provided.*
2.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided	Applicant batch No: T-01 **Comparator product:** T-day 5mg Tablet of M/s Sanofi-Aventis Batch No: AW 006
3.	Justify your acceptance criteria for dissolution test as NLT 60% of the labeled amount of Fexofenadine HCl is dissolved in 10 min; NLT 80% of the labeled amount of Fexofenadine HCl is dissolved in 30 min while USP has specified as NLT 60% (Q) of the labeled amount of Fexofenadine HCl dissolved in 10 min; NLT 80% (Q) of the labeled amount of Fexofenadine HCl dissolved in 30 min.	USP defines quantity Q, is the amount of dissolved active ingredient specified in the individual monograph. When we look at a Q value, we are looking at what percent has dissolved at that time. Thus, there is no difference between NLT 60% in 10 min and NLT 60% (Q) in 10 minutes and NLT 80% in 30 min and NLT 80 (Q) in 30 min. *However, USP general chapter of dissolution <711> defines S_1 stage of dissolution as each unit is not less than Q + 5% and did not revise dissolution acceptance criteria as per USP.*
4.	Submit acceptance criteria for release and shelf life specifications.	The firm has submitted acceptance criteria for release and shelf life specifications.
5.	Justify dissolution results in the submitted batch analysis since results are not complying USP monograph.	The firm has referred to USP definition of Q, as the amount of dissolved active ingredient specified in individual monograph. *The firm has not provided justification of dissolution results not complying USP monograph.*
6.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	The firm has submitted analytical method verification reports of drug product. *However, details of standard and sample preparation methods alongwith chromatograms of different tested parameters were not provided. The results of repeatability parameter show absorbance values while rest of the parameter gives values in peak area.*
7.	COA of primary / secondary reference standard including source and lot number shall be provided.	The firm has submitted COA of working standard from drug substance manufacturer with lot no. WS-Fex-210209.
8.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levocetirizine Dihydrochloride for the purpose of test/analysis

		and stability studies is granted. However, invoice is not cleared by AD (I&E) DRAP of field office.
9.	The submitted chromatograms do not differentiate between real time or accelerated stability studies time points of different batches.	Not submitted
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that *audit trail is maintained manually*.
11.	Submit copies of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copies of batch manufacturing record of stability batches.
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Decision of 317th meeting: Deferred for submission of following:

- Analytical method verification report of drug substance performed by drug product manufacturer as
- per requirement of section 3.2.S.4.3 of Form-5F.
- Performance of pharmaceutical equivalence and CDP studies with innovator/reference product.
- Justify acceptance criteria for dissolution test in the light of USP monograph.
- Justify dissolution results in the submitted batch analysis since results are not complying USP specifications.
- HPLC chromatograms of all time points of real time and accelerated stability studies.
- Analytical method verification reports for testing of drug product as per requirements of section 3.2.P.5.3 of Form-5F.

Firm's response: Firm has submitted following:

- Analytical method verification studies for drug substance performed by M/s Himark.
- Pharmaceutical equivalence & CDP studies in three dissolution mediums against the Telfast tablet.
- Revised dissolution limits as per USP monograph as under:
  - NLT 60(Q) i.e., 65% of the labelled amount of Fexofenadine HCl is dissolved in 10 minutes.
  - NLT 60(Q) i.e., 85% of the labelled amount of Fexofenadine HCl is dissolved in 30 minutes.
- Dissolution test has been repeated in 10minutes our results did not fall in S1 stage. However, in S2 stage our results qualify i.e., no dissolution result is below 60%.
- HPLC chromatograms for stability studies.

Analytical method verification report for drug product

Decision of 323rd meeting: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**

1400.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited., Plot # 37-A, Sundar Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited., Plot # 37-A, Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 288: Dated 04-01-2022
	Details of fee submitted	PKR 20,000/-: Dated 31-12-2020 PKR 10,000/-: dated 04-11-2021 .
	The proposed proprietary name / brand name	Levomark 500 mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin as hemihydrate…….500 mg
	Pharmaceutical form of applied drug	Light yellow oblong film coated tablet
	Pharmacotherapeutic Group of (API)	Flouroquinolones
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 × 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levofloxacin 500 mg Film-coated tablets by Accord Healthcare Limited UK (MHRA Approved).
	For generic drugs (me-too status)	Leflox 500 mg Tablet by Getz Pharma (Reg. No. 026164).
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019 Tablet (General & General Antibiotic) section.
	Name and address of API manufacturer.	M/s Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd., 333 Jiangnan Road, hengdian, Dongyang, Zhejiang Province, 322 118 PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levofloxacin hemihydrate is present in USP. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and impurities and water content have been performed, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (LFA-V-20120801ES, LFA-V-20120802ES, LFA-V-20120803ES)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control,

		process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established with comparator product **Leflox 500 mg Tablet** of M/s Getz Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). The firm has submitted comparative dissolution study with comparator product **Leflox 500 mg Tablet** of Getz Pharma in acidic media (pH 1.0-1.2) and pH 4.5 & phosphate buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical method verification reports have not been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Apeloa Kangyu Pharmaceutical Co. Ltd., 333 Jiangnan Road, hengdian, Dongyang, Zhejiang Province, 322118 PR China		
API Lot No.	KY-LFA-M20190968E		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-58	T-59	T-60
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2020	04-2020	04-2020
Date of Initiation	22-04-2020	22-04-2020	22-04-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. ZJ201190145 issued by China food & Drugs administration is attached and it is valid till 29-11-24.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levofloxacin hemihydrate for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches including raw data sheets, COAs, summary data sheets etc.

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

Sr. No.	Observations	Response by the firm
1.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of standard and sample preparation methods alongwith chromatograms in different tested parameters were not provided.*
2.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided	Applicant batch No: T-58 **Comparator product:** Leflox 500mg Tablet of M/s GETZ Pharma Batch No: LF-095
3.	The submitted CDP data showed less than 75% release in 30 min in all media, therefore, justify CDP data in the light of WHO Recommendations for conducting and assessing CDP wherein it is stated: "*In the case where 85% dissolution cannot be reached due to poor solubility of the API, the dissolution should be conducted until an asymptote (plateau) has been reached*".	The firm has revised comparative dissolution studies by adding 45 min time point in the studied dissolution media. *However, dissolution studies are not conducted until asymptote as per WHO recommendations.*
4.	Justify your acceptance criteria for dissolution test as NLT 80% of the labeled amount of Levofloxacin is dissolved in 30 min.	The firm has submitted that there is no difference between NLT 80% in 30 min and NLT 80% (Q) in 30 min. *However, USP general chapter of dissolution <711> defines S_1 stage of dissolution as each unit is not less than Q + 5% and accordingly did not revise dissolution acceptance criteria as per USP.*
5.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of standard and sample preparation methods alongwith chromatograms in different tested parameters were not provided.*
6.	The submitted copy of GMP certificate of API manufacturer is expired on 28-09-2021. Updated copy of GMP certificate shall be submitted.	The firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Telangana India valid up to 20-05-2023.
7.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levocetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted. However, invoice is not cleared by AD (I&E) DRAP of field office.
8.	The submitted chromatograms do not differentiate between real time or accelerated stability studies time points of different batches.	Not submitted.

9.	UV spectra of dissolution results alongwith raw data sheets for dissolution tests throughout stability data are required to be submitted.	Not submitted.
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that *audit trail is maintained manually.*
11.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Decision of 317th meeting: Deferred for submission of following:

- Analytical method verification report of drug substance performed by drug product manufacturer as
- per requirement of section 3.2.S.4.3 of Form-5F.
- Performance of pharmaceutical equivalence and CDP studies with innovator/reference product.
- Justify comparative dissolution studies in the light of WHO recommendations which recommend conduction of dissolution studies until asymptote if 85% dissolution could not be reached due to poor solubility of API
- Justify your acceptance criteria for dissolution test in the light of USP specifications.
- HPLC chromatograms of all time points of real time and accelerated stability studies.
- UV spectra alongwith raw data sheets for dissolution tests in stability study data.
- Analytical method verification reports for testing of drug product as per requirements of section 3.2.P.5.3 of Form-5F.

Firm's response: Firm has replied as under:

- Analytical method verification studies for drug substance performed by M/s Himark.
- Pharmaceutical equivalence & CDP studies in three dissolution mediums against the Leflox tablet till the time point where 85% release is achieved.
- Revised dissolution limits as per USP monograph as under:
  - NLT 80(Q) i.e., 85% of the labelled amount of Levofloxacin is dissolved in 30 minutes.
- Dissolution test has been repeated in 10minutes our results did not fall in S1 stage. However, in S2 stage our results qualify i.e., no dissolution result is below 60%.
- HPLC chromatograms & UV spectrums along with raw data sheets for stability studies.
- Analytical method verification report for drug product

Decision of 323rd meeting: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**

1401.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited., Plot 37-A, Sundar Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited., Plot 37-A, Sundar Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24082 Dated 01-09-2021
	Details of fee submitted	PKR 30,000/-: Dated 21-06-2021
	The proposed proprietary name / brand name	**Hikast 4 mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Montelukast Sodium eq. to Montelukast.....4 mg
	Pharmaceutical form of applied drug	Granules in sachet pack
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	1 ×14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Singulair® Paediatric 4 mg Granules by Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK (MHRA Approved).
	For generic drugs (me-too status)	Montiget powder Sachet 4 mg by M/s Getz Pharma, (Reg. No. 057746)
	GMP status of the Finished product manufacturer	New license granted on 26/09/2019 Sachet (General) section approved.
	Name and address of API manufacturer.	M/s Dhanuka Laboratories Ltd SP4-4, Industrial Area, Cyber City Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Montelukast Sodium is present in any United States Pharmacopeia. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and tests for related substances (unspecified and total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (STRHB 170001, STRHB 170002, STRHB 170003).
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications,

		analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against comparator product **Montiget Sachet** by M/s Getz Pharma by performing quality tests (Identification, Assay, pH, dissolution test, Uniformity of dosage unit & organic impurities). CDP – Not applicable
	Analytical method validation/verification of product	Method verification reports have not been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Dhanuka Laboratories Ltd., SP4-4, Industrial Area, Cyber City Keshwana Rajput, Kotputli, Shahpura, Jaipur-303108, Rajasthan, India.		
API Lot No.	MTS-2010009		
Description of Pack (Container closure system)	White to off white color suspension with sweet taste filled in sachet pack		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-103	T-104	T-105
Batch Size	100 Sachet	100 Sachet	100 Sachet
Manufacturing Date	11-2020	11-2020	11-2020
Date of Initiation	17-11-2020	17-11-2020	17-11-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. DC/A-2/WHO GMP/2019/35 issued by Drugs Control Organization Swasthya Bhawan Tilak Marg, Jaipur Rajasthan, India, issued on 17-01-2019 and valid for 3 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26-12-2019 is submitted wherein the permission to import different APIs Montelukast Sodium for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches including raw data sheets, COAs, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.

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

Sr. No.	Observations	Response by the firm
1.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of standard and sample preparation methods alongwith chromatograms in different tested parameters were not provided.*
2.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided	Applicant batch No: T-103 **Comparator product:** Montiget 4mg Sachet of M/s GETZ pharma Batch No: B656D03
3.	The reference formulation states granules for oral suspension for applied formulation. Clarification is required in manufacturing process and process control whether granules will be prepared in-house or otherwise.	The granules are prepared in-house by sieving the materials from appropriate mesh.
4.	Analytical method verification reports of each parameter like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	The firm has submitted analytical method verification reports of drug product. *However, details of standard and sample preparation methods alongwith chromatograms in different tested parameters were not provided.*
5.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26-12-2019 is submitted wherein the permission to import different APIs Montelukast Sodium for the purpose of test/analysis and stability studies is granted.
6.	The submitted chromatograms do not differentiate between real time or accelerated stability studies time points of different batches.	Not submitted.
7.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted that *audit trail is maintained manually.*
8.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Decision of 317th meeting: Deferred for submission of following:

- Analytical method verification report of drug substance performed by drug product manufacturer as
- per requirement of section 3.2.S.4.3 of Form-5F.
- Performance of pharmaceutical equivalence and CDP studies with innovator/reference product i.e., Singulair® Paediatric 4 mg Granules.
- HPLC chromatograms of all time points of real time and accelerated stability studies.
- Analytical method verification reports for testing of drug product as per requirements of section 3.2.P.5.3 of Form-5F.

Firm's response: Firm has replied as under:

- Analytical method verification studies for drug substance performed by M/s Himark.
- Pharmaceutical equivalence & CDP studies in three dissolution mediums against the Montiget sachet stating that Singulair Paediatric granules by Organon Pharma UK is not available in Pakistan.
- HPLC chromatograms for stability studies.
- Analytical method verification report for drug product

• COA of reference standard of "Montelukast Dicyclohexylamine"		
Decision of 323rd meeting: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1402.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Private Limited., Plot 37-A, Sundar Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s Himark Laboratories Private Limited., Plot 37-A, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32453 Dated 10-12-2021
	Details of fee submitted	PKR 30,000/-: Dated 29-11-2021
	The proposed proprietary name / brand name	**Citromark 5 mg film coated tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levocetirizine dihydrochloride…….5 mg
	Pharmaceutical form of applied drug	White color round shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 × 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XYZAL Levocetirizine hydrochloride 5 mg film coated tablet by M/s UCB Pharma (Approved in TGA)
	For generic drugs (me-too status)	T-Day 5 mg film coated Tablet by M/s GSK Consumer Healthcare (Reg. No. 083964)
	GMP status of the Finished product manufacturer	New license granted on 26-09-2019. Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Metrochem API Private Limited., Factory: Unit-I, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla Hyderabad-500 055, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levocetirizine dihydrochloride is present in USP. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and specific optical rotation, heavy metals and enantiomeric purity by HPLC, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C /75% ± 5% RH for 6 months Batches: (LCZ/A/200801001, LCZ/A/200801002, LCZ/A/200801003)
	Module-III (Drug Product):	The firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against comparator product **T-day 5 mg tablet** by GSK consumer healthcare by performing quality tests (Identification, assay, dissolution, uniformity of dosage form). CDP has been performed against the same in acidic media (pH 1.0-1.2) and pH 4.5 & phosphate buffer (pH 6.8). The values for f_1 and f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Metrochem API Private Limited., Factory: Unit-I, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla Hyderabad-500 055, India		
API Lot No.	LUVPC21027		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 tab	1500 tab	1500 tab

Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	12-05-2021	12-05-2021	12-05-2021
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate No. 1296/DD/DCA/VSP/2020 issued by Deputy Director & Certifying Authority drugs control administration Visakhapatnam Region India valid up to 28-09-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levocetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches including raw data sheets, COAs, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	The submitted COA from drug product manufacturer shows pH of sample solution as 4.42 which is not within the limit of 1.2 to 1.8.	The firm has submitted fresh certificate of analysis with revised result of pH as 1.5 and document does not contain date of analysis.
2.	Analytical method verification reports of parameters like specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of standard and sample preparation methods alongwith chromatograms of different tested parameters were not provided.*
3.	Details of batch numbers of applicant and comparator product in pharmaceutical equivalence are required to be provided	Applicant batch No: T-01 **Comparator product:** T-day 5mg Tablet of M/s GSK Batch No: HH9T
4.	The submitted CDP data showed less than 75% release in 30 min in all media, therefore, justify CDP data in the light of WHO Recommendations for conducting and assessing CDP wherein it is stated: "*In the case where 85% dissolution cannot be reached due to poor solubility of the API, the dissolution should be conducted until an asymptote (plateau) has been reached*".	The firm has revised comparative dissolution studies by adding 45 min time point in the studied dissolution media. The results show initial release of 50% at 30 min while the drug release occurred more than 90% at 45 min time point in all media. *Moreover, dissolution studies are not conducted until asymptote as per WHO recommendations.*
5.	Analytical method verification reports of each parameter like specificity, accuracy and	The firm has submitted analytical method verification reports of drug substance performed by drug product manufacturer. *However, details of*

	repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	*standard and sample preparation methods alongwith their concentrations in different tested parameters were not provided.*
6.	The submitted copy of GMP certificate of API manufacturer is expired on 28-09-2021. Updated copy of GMP certificate shall be submitted.	The firm has submitted copy of GMP certificate issued by Drugs Control Administration Government of Telangana India valid up to 20-05-2023.
7.	Submitted invoice for the procurement of drug substance is not attested by AD (I & E). Clarification is required.	The firm has submitted copy of letter No.17133/2019/DRAP-AD-CD(I&E) dated 26/12/2019 is submitted wherein the permission to import different APIs including Levocetirizine Dihydrochloride for the purpose of test/analysis and stability studies is granted. However, invoice is not cleared by AD (I&E) DRAP of field office.
8.	The submitted chromatograms do not differentiate between real time or accelerated stability studies time points of different batches.	Not submitted
9.	UV spectra alongwith raw data sheets for dissolution tests in stability study data are required to be submitted.	Not submitted.
10.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.

Decision of 317th meeting: Deferred for submission of following:

- Analytical method verification report of drug substance performed by drug product manufacturer as
- per requirement of section 3.2.S.4.3 of Form-5F.
- Performance of pharmaceutical equivalence and CDP studies with innovator/reference product.
- Justify comparative dissolution studies in the light of WHO recommendations which recommend conduction of dissolution studies until asymptote if 85% dissolution could not be reached due to poor solubility of API.
- HPLC chromatograms of all time points of real time and accelerated stability studies.
- UV spectra alongwith raw data sheets for dissolution tests in stability study data.
- Analytical method verification reports for testing of drug product as per requirements of section 3.2.P.5.3 of Form-5F.

Firm's response: Firm has submitted following:

- Pharmaceutical equivalence & CDP studies in three dissolution mediums against the Xyzal tablet 5mg till the time point where 85% release is achieved.
- HPLC chromatograms & UV spectrums along with raw data sheets for stability studies.
- Analytical method verification report for drug product

Decision of 323rd meeting: Approved.

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

1403.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13224 dated 30/05/2022
	Details of fee submitted	PKR 75,000/-: dated 26/05/2022
	The proposed proprietary name / brand name	**Tramacet 75mg/650mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCl ……... 75mg Paracetamol …… 650mg
	Pharmaceutical form of applied drug	Blue colored, oblong plain film coated tablet
	Pharmacotherapeutic Group of (API)	Opiate analgesic & NSAIDS
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's, 2x10's, 3x10's, As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tramadol/Paracetamol 75 mg / 650 mg Tablets by M/s Aspire Pharma Ltd. UK.
	For generic drugs (me-too status)	Tonoflex-P Forte tablet by M/s Sami Pharmaceuticals, Reg. No. 094798
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 70/2021-DRAP (FID/2061717-540) dated 08-09-2021.
	Name and address of API manufacturer.	**For Tramadol** M/s Proto Chemicals AG Tschachen 2,8756 Mitlödi (Glarus Süd), Switzerland. **For Paracetamol** M/s Carry For Pharmaceutical Private limited Plot. #: E-81, North Western industrial Zone. Port Qasim,Karachi, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Tramadol & paracetamol is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**For Tramadol HCl** Stability study conditions: Real time: 30°C ± 2°C/75% ± 5%RH for 60 months

		Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (E5846, E5861, E5862) **For Paracetamol** Stability study conditions: Real time: 30°C ± 2°C/65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C/75% ± 5%RH for 6 months Batches: (CPCM1908-001, CPCM1908-002, CPCM19010-003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure (including dissolution testing at acidic, acetate and buffer media), batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Tonoflex-P Forte of M/s Sami Pharmaceuticals by performing only Identification and Assay tests. CDP has been performed against the same brand that is Tonoflex-P Forte tablet by Sami Pharmaceuticals in Acidic media (pH-1.2), Acetate Buffer(pH-4.5) & Phosphate Buffer (pH 6.8). The values for f_2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**For Tramadol** M/s Proto Chemicals AG, Tschachen 2, 8756 Mitlödi (Glarus Süd), Switzerland. **For Paracetamol** M/s Carryfor Pharmaceuticals (Pvt) limited, Plot. #: E-81, North Western Industrial Zone, Port Qasim, Karachi.		
API Lot No.	Not Mentioned		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TTP001	TTP002	TTP003
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	16-11-2021	17-11-2021	18-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**For Tramadol HCl** Copy of GMP certificate No. 20-0286 issued by Swiss agency for Therapeutic Products. **For Paracetamol** Copy of GMP certificate No.149/2020-Drap (K) dated 16-11-2020 issued by Drug Regulatory authority of Pakistan.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of DRAP attested invoice no. CS-21/02668 dated 01/04/2021 for Tramadol HCl 150kg is submitted. • Copy of local sales tax invoice No. 378 dated 10-10-2021 for Paracetamol 1000kg is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted the audit trail of 03 days for HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Observations Communicated	Response by the applicant on WhatsApp
i.	Submit copy of valid DML	Copy of DML No. 000789 renewed w.e.f. 03-02-2019 is submitted. However, the name of manufacturer in previous DML was **M/s Wimits Pharmaceuticals** while in new DML, it is **M/s Wimits Pharmaceuticals (Pvt.) Ltd.**
ii.	Submit clarification regarding out of limit Relative Standard Deviation RSD of Accuracy testing in verification of analytical procedures for Tramadol HCl.	The firm has submitted the revised RSD limits for verification of analytical procedures.
iii.	Submit clarification as Assay specification limits used in drug substance analysis of Paracetamol performed by drug product manufacturer are in accordance with BP monograph (99-101%) while in stability study data Assay specification limits are as per USP monograph (98-102%).	The firm submitted that the supplier complies with both BP & USP monograph and they had followed more stringent limit for the analysis i.e. 99-101%.
iv.	Clarification of not submitting compatibility studies as there is difference in qualitative formulation of applied product and Innovator product.	The firm has submitted the tabulated results of compatibility studies.
v.	Submit Pharmaceutical Equivalence as per pharmacopoeia monograph of the product.	The submitted Pharmaceutical Equivalence does not include Uniformity of Dosage Unit Test.
vi.	Maximum holding time of bulk before final packing is not submitted.	The firm submitted that the batch is processed right after dispensing and the bulk is not held for too long and batch is completed in 24hrs.
vii.	APIs lot no. is not indicated in stability study data.	The firm has submitted the revised stability data sheet indicating API Lot No. However, the mentioned lot of Tramadol HCL is different from the lot tested by drug product manufacturer.
viii.	Submitted DRAP attested invoice of Tramadol HCl is from Chemo S.A. Lugano Branch, Via F. Pelli 17, P.O. Box 6901, Lugano, Switzerland while the manufacturer of Tramadol HCl as per dossier is M/s Proto Chemicals AG, Tschachen 2, 8756 Mitlödi (Glarus Süd), Switzerland.	The firm submitted that Chemo S.A. Lugano is trader while Proto Chemicals is API manufacturer.
ix.	API lot numbers are not mentioned on local sales invoice of Paracetamol.	The firm has submitted the revised sales tax invoice indicating batch number of API. However, the invoice indicates the manufacturing date of API as **09-12-2021** while the record of trial batch of drug product manufactured from this API indicates the manufacturing date as **November, 2021**.

x.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing are not submitted.	The firm has submitted the audit trail of 03 days for HPLC.

Decision: The Board deferred the case for following points;

- Clarification since the firm has submitted the invoice indicating batch number of Paracetamol, however, the invoice indicates the manufacturing date of Paracetamol (drug substance) as 09-12-2021 while the record of trial batch of drug product manufactured from this lot indicates that the manufacturing date is November, 2021.
- Clarification since the firm has submitted the revised stability data sheet indicating the Lot No of Tramadol HCl, however, the mentioned lot of Tramadol HCl is different from the lot used for the product development.

Firm's response: Firm has sumitted declaration from the M/s Carryfor Pharmaceutical Pvt. Ltd., as under:
"We M/s Carryfor Pharmaceutical Pvt. Ltd., hereby undertake that there are some clerical mistakes in mentioning invoice date, manufacturing date, manufacturing date and expiry date of paracetamol batch# CPCM2112-058 issue toM/s Wimits PharmaceuticalPvt. Ltd. The correct details are as under:
Batch# CPCM2112-058
Mfg. date: 09-10-2021
Exp. Date: 0-10-2025
Invoice date: 31-10-2021

Decision of 323rd meeting: Approved.

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

1404.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 3185 dated 02-02-2022
	Details of fee submitted	Rs.30,000/- dated 20-12-2021
	The proposed proprietary name / brand name	**Acetaget 500mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Paracetamol USP…..500mg
	Pharmaceutical form of applied drug	White colored, round shaped, core tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	20 x 10's 50 x 10's
	Proposed unit price	Rs. 540 (20 x 10's)/-, Rs. 1350 (50 x 10's)/-

	The status in reference regulatory authorities	Paracetamol 500mg Tablets by M/s Dr. Max Pharma Netherlands.
	For generic drugs (me-too status)	Panadol 500mg Tablets Manufactured by M/s Pharmatec Pakistan (Pvt) Ltd and marketed by M/s GlaxoSmithKline Pakistan. (Reg. No.: 101138)
	GMP status of the Finished product manufacturer	Last GMP Inspection dated 03-12-2021 concludes that M/s Getz Pharma Pvt. Ltd. is considered to be operating at an acceptable level of compliance of GMP requirements. Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	**M/s HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD.** Southeast Xijingming Village, Donganzhuang Township, Shenzhou County, Hengshui City, Hebei Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (31512021, 31512025, 31512026)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Paracetamol 500mg Tablets by M/s Pharmatec Pakistan (Pvt) Ltd and marketed by M/s GlaxoSmithKline Pakistan, by performing quality

		tests (Appearance, Average weight, Disintegration time, Assay and Dissolution). CDP has been performed against the same brand that is Paracetamol 500mg Tablets by Pharmatec Pakistan (Pvt) Ltd and marketed by GlaxoSmithKline Pakistan, in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including, system suitability, specificity, linearity, accuracy, precision repeatability, Intermediate precision and robustness.

STABILITY STUDY DATA

Manufacturer of API	M/s HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD. Southeast Xijingming Village, Donganzhuang Township, Shenzhou County, Hengshui City, Hebei Province, China.		
API Lot No.	0000170088		
Description of Pack (Container closure system)	Alu-PVDC blister packed in unit carton (20 x 10's),(50 x 10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 & 12 (Months)		
Batch No.	551DS01	551DS02	551DS03
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	05-10-2020	12-10-2020	12-10-2020
Date of Initiation	12-10-2020	13-10-2020	13-10-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product for Estine (Ebastine) Tablets 10mg & 20mg on 6th May, 2019. Further, the said panel inspection report was discussed in 289th Drug Registration Board meeting held on 14th – 16th May 2019. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.

<table>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of certificate of Good Manufacturing Practices (GMP) issued by Hebei Food and Drug Administration. (valid till 08-07-2023).</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>31909052</td><td>1909ZP24</td><td>500kg</td><td>25-10-2019</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
</table>

Remarks of Evaluator:

Section #.	Deficiencies	Firm's response
3.2.S.4	• Chromatographic conditions for the performance of Assay test, in the analytical procedure submitted from drug substance manufacturer, are different form that recommended by USP monograph of "Acetaminophen". • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for shall be submitted.	This is to bring to your kind attention that API manufacturer has made minor adjustment in the test procedure for Assay as described in USP monograph. The adjustment is made to make analytical method simpler and efficient. The analytical method is further validated that confirms that proposed method is suitable for intended use. Moreover, M/s Getz Pharma has developed test procedure for Acetaminophen in accordance with USP monograph and Analytical Method Verification studies have been performed accordingly. Please refer to Annex 1 for Analytical Method Verification studies including specificity, linearity, repeatability and range performed by the Drug Product manufacturer. This is to bring to your kind attention that we have used 100% API without any placebo in Analytical Method Verification Studies of Acetaminophen; therefore, requirement of accuracy is not applicable. Further, we have performed linearity to check area response of the sample as the concentration

		of the sample raised within working range of sample i.e., 50% - 150%.
3.2.S.5	COA of reference/working standard shall be submitted, used for the analysis of drug substance by M/s Getz pharma.	COA of reference/working standard used for the analysis of drug substance by M/s Getz Pharma has been submitted.
3.2.P.5	Submitted drug product specifications refer to USP, whereas the analytical procedure for Assay test is not as per USP monograph of "Acetaminophen tablets". Justification shall be submitted in this regard. Analytical method verification studies are not for the Assay method as recommended by USP monograph of "Acetaminophen tablets".	This is to inform you that the concentration of standard and sample solution preparation are exactly same as recommended in USP monograph of "Acetaminophen Tablets. However, we have modified chromatographic conditions for Assay method using chromatographic conditions for Related Substances since USP allows the use of alternate methods like in case of ease of testing. Therefore, we have adopted different chromatographic condition for Assay method. Further we have completely validated said Assay method and found to be accurate and precise that will produce equivalent results as USP. • In contrary to the claim of firm the alternate method adopted for Assay test is not as per method of related substances.
3.2.P.8.3	Assay test in the submitted stability studies have not been conducted as per analytical procedure recommended by "Acetaminophen tablets". Justification shall be submitted in this regard.	This is to inform you that for stability studies we have followed different Assay method from USP as discussed in point 3.2.P.5. Further, we have completely validated said Assay method and found to be accurate and precise that will produce equivalent results as USP.

Decision of 320th meeting: The Board Deferred the case for scientific justification for performing assay testing during the stability studies using a different method than described by USP.

Firm's response: This is to bring to your kind attention that we have developed the Assay method as per USP monograph of "Acetaminophen tablets" along with performance of analytical method verification studies of Assay method as per USP monograph. Please refer to Annex 1 for Updated Specification, Analytical Method and Assay Method verification report of Acetaget Tablets 500mg as per USP monograph.

This is to bring to your kind information that next interval of Long term stability studies i.e., 24 Months will be due in October 2022 Therefore, we have performed Assay Method testing as per USP monograph on stability batches and reports with chromatograms are attached.

Decision of 323rd meeting: Approved.

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

Case no. 04 Registration applications of Import (Human) drugs

a. New cases

1405.	Name, address of Applicant / Importer	M/s Bristol Mayer Biotech Pakistan, 73-B, Guldasht town, Zarrar Shaheed road, Lahore cantt.
	Details of Drug Sale License of importer	License No: 05-352-0068-029407D Address: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt. Address of Godown: NA Validity: 07-04-2022 Status: License to sell drugs as a distributor Renewal: Applied for renewal. Receipt is attached.
	Name and address of marketing authorization holder (abroad)	M/s VEM İLAÇ San. ve Tic. A.Ş. TURKEY Söğütözü Mahallesi 2177. Cadde No: 10B/49 Cankaya/Ankara/Turkey.
	Name, address of manufacturer(s)	M/s VEM İLAÇ San. ve Tic. A.Ş. TURKEY Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Fatih Bulvarı No:38 Kapaklı/TEKİRDAĞ/TURKEY.
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The **f**irm has submitted original, legalized copy of CoPP certificate (No. 2021/464) dated 11-02-2021 issued by Turkish Medicines and Medical Devices Agency, Republic of Turkey for Coplanin 200mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **Validity:** 11-02-2023. Firm has submitted legalized copy of GMP certificate (No. TR/GMP/2020/215) **Validity:** 09-09-2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from M/s Vem ilac Turkey. The authorization letter is valid till 19-03-2026.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 17864 Dated: 18-09-2019

		Dy. No. 33079 Dated: 17-12-2021
	Details of fee submitted	PKR 50,000/- Dated: 16-09-2019 PKR 50,000/- Dated: 05-01-2019
	The proposed proprietary name / brand name	**Coplanin 200mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Teicoplanin…….200mg and ampoule containing 3 ml water for injection.
	Pharmaceutical form of applied drug	Lyophilized powder for solution for injection
	Pharmacotherapeutic Group of (API)	Antibiotic Class: Glycopeptide
	Reference to Finished product specifications	Current EP
	Proposed Pack size	1's
	Proposed unit price	Rs 2500 per vial
	The status in reference regulatory authorities	Targocid 200mg powder for solution for injection/infusion (MHRA approved)
	For generic drugs (me-too status)	Ticozid 200mg Injection of Bosch pharma (Reg # 050514).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co; Ltd. China. Address: Jiangyin Industrial Concentration zone, Fuzhou city, Fujian province, P.R. China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 5°C ± 3°C. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence	The firm has submitted pharmaceutical equivalence study with reference product Targocid 200mg IV/IM lyophilized powder for injection (batch # A3367).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	10 ml nominal Volume, Type I (USP) colorless glass vial. Water for injection is filled to 3 ml volumetric type 1 colorless glass ampoule. Gray bromobutyl lyophilized stopper and green flip-off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability study data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ± 2°C / 75% ± 5% RH. The real time stability study data of 3 batches is for 24 months. Batch # 708001 Batch # 710002 Batch # 710003
Evaluation by PEC:		
1406.	Name, address of Applicant / Importer	M/s Bristol Mayer Biotech Pakistan, 73-B, Guldasht town, Zarrar Shaheed road, Lahore Cantt.
	Details of Drug Sale License of importer	License No: 05-352-0068-029407D Address: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt. Address of Godown: NA Validity: 07-04-2022 Status: License to sell drugs as a distributor Renewal: Applied for renewal. Receipt is attached.
	Name and address of marketing authorization holder (abroad)	M/s VEM İLAÇ San. ve Tic. A.Ş. TURKEY Söğütözü Mahallesi 2177. Cadde No: 10B/49 Cankaya/Ankara/Turkey.
	Name, address of manufacturer(s)	M/s VEM İLAÇ San. ve Tic. A.Ş. TURKEY Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Fatih Bulvarı No:38 Kapaklı/TEKİRDAĞ/TURKEY.
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** The **f**irm has submitted original, legalized copy of CoPP certificate (No. 2021/464) dated 11-02-2021 issued by Turkish Medicines and Medical Devices Agency, Republic of Turkey for Coplanin 200mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. **Validity:** 11-02-2023. Firm has submitted legalized copy of GMP certificate (No. TR/GMP/2020/215)

		Validity: 09-09-2022. CoPP also declares the details of accompanying diluent as follows: 3ml WFI in Type-I colourless glass ampoule.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from M/s Vem ilac Turkey. The authorization letter is valid till 19-03-2026.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 17863 Dated: 18-09-2019 Dy. No. 33080 Dated: 17-12-2021
	Details of fee submitted	PKR 50,000/- Dated: 16-09-2019 PKR 50,000/- Dated: 05-01-2019
	The proposed proprietary name / brand name	**Coplanin 400mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Teicoplanin…….400mg and ampoule containing 3 ml water for injection.
	Pharmaceutical form of applied drug	Lyophilized powder for solution for injection
	Pharmacotherapeutic Group of (API)	Antibiotic Class: Glycopeptide
	Reference to Finished product specifications	Current EP
	Proposed Pack size	1's
	Proposed unit price	Rs 4500 per vial
	The status in reference regulatory authorities	Targocid 400mg powder for solution for injection/infusion (MHRA approved)
	For generic drugs (me-too status)	Ticozid 400mg Injection of Bosch pharma (Reg # 050514).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co; Ltd. China. Address: Jiangyin Industrial Concentration zone, Fuzhou city, Fujian province, P.R. China.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 5°C ± 3°C. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence	The firm has submitted pharmaceutical equivalence study with reference product Targocid 400mg IV/IM lyophilized powder for injection (batch # A3367).
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	20 ml Nominal Volume, Type I (USP) colorless glass vial. Water for injection is filled to 3 ml volumetric type 1 colorless glass ampoule. Gray bromobutyl lyophilized stopper and green flip-off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability study data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ± 2°C / 75% ± 5% RH. The real time stability study data of 3 batches is for 24 months. Batch # 707001 Batch # 712002 Batch # 806002

Evaluation by PEC:

Sr.#	Section	Observation	Firm's response
1.		Differential fee of PKR 50,000/- shall be submitted since the applied formulation is already registered in Pakistan.	Submitted
2.	**1.3.4**	Submit copy of valid drug sale license by respective licensing authority.	Firm has submitted copy of Valid DSL as per following details: License No: 05-352-0068-029407D Address: 73-B, Guldasht Town, Zarrar Shaheed Road, Lahore Cantt.

			Address of Godown: NA Validity: 07-04-2027 Status: License to sell drugs as a distributor
3.	**1.5.6**	Mention the reference specifications of finished drug product since the applied drug product is not present in available EP.	Firm has stated that the specifications in section 1.5.6 were erroneously mentioned for drug substance.
4.	**3.2.S.4.1 & 3.2.S.4.2**	Provide copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by both Drug substance & Drug Product manufacturer.	Submitted.
5.	**3.2.S.4.3**	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Submitted
6.	**3.2.P.2.**	• Submit pharmaceutical equivalence of the applied drug with the reference product by comparing results of all the quality tests of the developed formulation and the reference product. • Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product.	• Submitted
7.	**3.2P.5.1**	You have mentioned reference of finished product specifications as current EP while the product monograph is not present in available pharmacopoeia.	The product complies with in house specifications, the EP monograph was referred for drug substance
8.	**3.2.P.8**	• There is also a significant change in the accelerated stability data of drug product (Coplanin 400mg Injection, batch number 806002) at 6th month time point in the assay of teicoplanin. Justification is required.	• The firm has stated that saccelerated stability study results were within acceptable limits and also referred to the long term stability studies.

Decision: Registration Board approved the applications of Coplanin 200mg Injection & Coplanin 400mg Injectionwith Innovator's specifications as per policy for inspection sof manufacturer abroad. The firm shall submit fee of Rs. 7500/- for each strength for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

b. Deferred cases

1407	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block ''C'', Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0066-016174-D **Address: 793-D, Block-C, Faisal Town Lahore**

		Validity: 06-02-2022 **Status:** License to sell drugs as a distributor **Address of Godown:** N/A
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address:Kathali ,Bhaluka,Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular RoaD, Motijheel Dhaka, Bangaldesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address:Kathali ,Bhaluka,Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular RoaD, Motijheel Dhaka, Bangaldesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) Firm has submitted original legalized COPP (DA/6-110/2016/3296) issued on 01-June-2020 Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited.	
	Details of letter of authorization / sole agency agreement •	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 2037746 Dated 03-03-2020
	Details of fee submitted	Rs.100,000/- Dated 03-03-2020
	The proposed proprietary name / brand name	**Niraparix 100mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Niraparib Tosylate Monohydrate INN equivalent to Niraparib 100mg
	Pharmaceutical form of applied drug	capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house

	Proposed Pack size	90's in HDPE bottle
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Zejula 100mg Capsule (GlaxoSmithKline limited, Ireland)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Anqing World Chemical Company Limited No.21 Huancheng west road AnQing County, AnHui Province China
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product of Zejula 100mg Capsule (GlaxoSmithKline limited) has been submitted has been submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies of the drug product.
	Container closure system of the drug product	White HDPE bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submiited stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months.

		Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Remarks of Evaluator[II]:

Section #.	Deficiencies	Firm's response
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studiesjasm, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture	Drug product manufacturer has submitted, specifications, analytical procedure, analytical method verification studies & COAs for drug substance.
3.2.P.1	• Qualitative composition of applied product is not same as per that of the innovator product.	• The excipients used complies with current pharmacopoeial monographs. These excipients are pharmaceutically inert substance and we have used these excipients below the IIG limit of FDA database as well as we have done extensive analysis of the product afer formulation and found satisfactory result of assay, dissolution results & impurity profile. Also w have done stability study during developmeht stage and found satisfactory result of the product. So we can conclude that these excipients are not incompatible with the API.
3.2.P.2	Compatibility studies of the Drug Substance(s) with excipients shall be submitted, since the qualitative composition of the formulation is not similar to innovator / reference product.	• The excipients used complies with current pharmacopoeial monographs. These excipients are pharmaceutically inert

		substance and we have used these excipients below the IIG limit of FDA database as well as we have done extensive analysis of the product afer formulation and found satisfactory result of assay, dissolution results & impurity profile. Also w have done stability study during developmeht stage and found satisfactory result of the product. So we can conclude that these excipients are not incompatible with the API.
3.2.P.2.2.1	• Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	• Firm has referred to the Bio equivalence studies of applied prodyuct performed as an open label, balanced, randomized, two-treatment, two sequence, two-period, crossover oral bioequivalence study of single dose of Niraparix capsule against Zejula capsule of m/s tesaro UK ltd.
3.2.P.5.1	• US FDA review document of the Innovator product i.e., Zejula, specifies the dissolution limit as "NLT Q in 45 minutes", whereas submitted specifications declare the dissolution limits as "NLT 70% in 60 minutes". Justify the variation in time point of dissolution.	• For dissolution method, we have used US FD Adatabase for medium, apparatus, volume and time point. However, please note tha, for dissolution time point we slected as 60 minutes. Based n the US FDA databse, dissolution tim endpoint covered 60 minutes in method of analysis.
3.2.P.8	• Accelerated stability studies of batch# 3830004, reflect significant change of in Assay results. • Following shall be submitted: i. Analytical record for stability studies including raw data sheets, chromatograms etc. ii. Complete batch manufacturing record. iii. GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority.	• Not replied against this point. • Analytical record for stability data not submitted. • BMRs have been submitted. • Submitted GMP certificate (No. NP122019) is not verifiable form the NMPA web site.

Decision: Deferred for following:

- Scientific justification for difference in dissolution limits in terms of %age released and time point from that recommended by the US FDA for innovator product along with comparison of disintegration & release profile of the applied product & innovator product.
- Submission of valid GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority.

Firm's response: Regarding dissolution testing FDA provide harmonized database for dissolution parameter and innovator develop their product as in-house parameter. Disintegration of the product is maximum 6 minutes, so active availability in the solution is fast and we perform the comparative dissolution study (release profile) with innovator product and found similar with the innovator.
Firm has submitted results of disintegration test of 6 batches wherein all results are within 5 minutes. Firm has stated that the disintegration of Niraparix Capsule is maximum 5 minutes, so the active is able to reach in absorption site very fast which is required for Bioavailability.

Decision of 323rd meeting: Approved with Innovator's specificatiosn as per policy for inspection of manufacturers abroad. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

- **Registration letter will be issued upon submission of performance of dissolution testing as per revised specifications according to that recommended by innovator drug product.**

1408	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D, Block ''C'', Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174-D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2022 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/A Toyenbee Circular Road Motijheel Dhaka Bangladesh
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/A Toyenbee Circular Road Motijheel Dhaka Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) Firm has submitted original legalized COPP (DA/6-110/2016/3292) issued on 01-June-2020 Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted.	
	Details of letter of authorization / sole agency agreement • Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.	

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 7092 dated 03-03-2021
	Details of fee submitted	Rs.50,000/- dated 01-02-2021
	The proposed proprietary name / brand name	**Hernix 40mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Neratinib Maleate equivalent to Neratinib ……. 40mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	180's in HDPE bottle
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Nerlynx 40mg (Pierre Fabre Medicament , France)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance..
	Name, address of drug substance manufacturer	Beijing Mesochem Technology Co., Ltd. Floor 23, Building 9, Lippo Plaza Economic and Technological Development Zone Beijing
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure,

		general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25±2ºC, 60%±5%RH. The stability study data is till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Nerlynx 40mg (Pierre Fabre Medicament, France) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months.

Remarks of Evaluator[II]:

Section #.	Deficiencies	Firm's response
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	• Drug product manufacturer has submitted, specifications, analytical procedure, analytical method verification studies & COAs for drug substance.

	• Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studiesjasm, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture	
3.2.P.1	• Qualitative composition of applied product is not same as that of the innovator product.	• The excipients used complies with current pharmacopoeial monographs. These excipients are pharmaceutically inert substance and we have used these excipients below the IIG limit of FDA database as well as we have done extensive analysis of the product afer formulation and found satisfactory result of assay, dissolution results & impurity profile. Also w have done stability study during developmeht stage and found satisfactory result of the product. So we can conclude that these excipients are not incompatible with the API.
3.2.P.2	Compatibility studies of the Drug Substance(s) with excipients shall be submitted, since the qualitative composition of the formulation is not similar to innovator / reference product.	• The excipients used complies with current pharmacopoeial monographs. These excipients are pharmaceutically inert substance and we have used these excipients below the IIG limit of FDA database as well as we have done extensive analysis of the product afer formulation and found satisfactory result of assay, dissolution results & impurity profile. Also w have done stability study during developmeht stage and found satisfactory result of the product. So we can conclude that these excipients are not incompatible with the API.
3.2.P.5.1	• US FDA review document of the Innovator product i.e., Nerlynx,	• The dissolution time for hernix tablet ha sbeen slected

	specifies the dissolution limit as "NLT Q in 30 minutes", whereas submitted specifications declare the dissolution limits as "NLT 75% in 45 minutes". Justify the variation in time point of dissolution. • Submitted specifications does not include test of content uniformity by way of Assay.	45 minutes as perthe british Pharmacopeoia guidline, reference chapter monographof the BP in the dissolution tests for tablets & capsules, Appendix XII B1. I nthe reference chapter it I smentioned that , "Unless otherwise indicated in th emongraph, withdraw samples at 45 minutes". Hence, we have selected 45 minutes as a sungle time point.
3.2.P.5.4	• Test of content uniformity by way of Assay has not been performed at the time of batch release.	• Firm has submitted revised finished product specifications including test of content uniformity and committed to provide COA from next commercial batches as per revised specifications.
3.2.P.8	• Following shall be submitted: i. Analytical record for stability studies including raw data sheets, chromatograms etc. ii. Complete batch manufacturing record.	• Submitted.

Decision of 320th meeting: Deferred for following:

- Scientific jusytification for difference in dissolution limits in terms of %age released and time point from that recommended by the US FDA for innovator product along with comparison of disintegration & release profile of the applied product & innovator product.

Firm's response: Regarding dissolution testing FDA provide harmonized database for dissolution parameter and innovator develop their product as in-house parameter. Disintegration of the product is maximum 3 minutes, so active availability in the solution is fast and we perform the comparative dissolution study (release profile) with innovator product and found similar with the innovator.
Firm has submitted results of disintegration test of 10 batches wherein all results arewithin 2 minutes.Firm has stated that the disintegration of Hernix Tablet is maximum 2 minutes, so the active is able to reach in absorption site very fast which is required for Bioavailability.

Decision of 323rd meeting: Approved with Innovator's specificatiosn as per policy for inspection of manufacturers abroad. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

- **Registration letter will be issued upon submission of performance of dissolution testing as per revised specifications according to that recommended by innovator drug product.**

1409.	**Name, address of Applicant / Importer**	**M/s 2 World Traders Pakistan. 55/2, Main Khayaban-e-Hafiz, DHA, Karachi, Pakistan**

	Details of Drug Sale License of importer	**License No:** 316 **Address:** 55/2 Main Khayaban-e-Hafiz Phase-V, DHA Karachi Pakistan **Address of Godown:** NA **Validity:** 15-03-2023 **Status:** Drug License by way of Whole Sale **Renewal:** Valid
	Name and address of marketing authorization holder (abroad) as per COPP	BIOMEDICA FOSCAMA Industria Chimico-Farmaceutica, S.p.A. Via Morolense n.87, 03013 Ferentino (FR) Italy.
	Name, address of manufacturer(s) as per COPP	BIOMEDICA FOSCAMA Industria Chimico-Farmaceutica, S.p.A. Via Morolense n.87, 03013 Ferentino (FR) Italy.
	Name of exporting country	Italy
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (N^{o}CPP/2021/756) dated 02-04-2021 issued by AIFA (Agenzia Italiana Del Farmaco) for TAD (Glutathione 600mg. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection. **GMP;** Firm has submitted the legalized copy of GMP certificate (No: IT/84/H/2020) which was valid till 31-12-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted attested copy of Import and Distribution Agreement between Biomedica Foscama and 2 World Traders Pakistan for the applied product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 27041 dated 30-09-2021
	Details of fee submitted	PKR 75,000/-:Slip # 944857553239 10-08-2021
	The proposed proprietary name / brand name	**TAD 600mg dry powder injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Glutathione as sodium …….600mg

	Pharmaceutical form of applied drug	White lyophilized powder packed in moulded clear type-3 vials along with 4ml solvent
	Pharmacotherapeutic Group of (API)	Antidote ATC Code: V03AB32
	Reference to Finished product specifications	European Pharmacopoeia
	Proposed Pack size	10 vials with 10 (4ml) solvent ampoules (WFI)
	Proposed unit price	As per pricing committee.
	The status in reference regulatory authorities	TAD **(AIFA** Approved) complies EU Pharmacopoeia.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Biomedica Foscama Industria Chimico-Farmaceutica S.P.A (Italy)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API for accelerated at $40^{o}C \pm 2^{o}C$ / 75% ± 5% RH for 6 months as well as Long term testing which is conducted at $25^{o}C \pm 2^{o}C$ / 65% ± 5% RH. The stability study data is till 36 months at $\leq 25°C$.
	Module-III Drug Product:	Firm has submitted data of drug product and solvent (WFI) separately, including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not applicable being the innovator product

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	API: Type III glass vials with chlorobutyl stoppers Aluminium oversealed Solvent: Type-I glass ampoules
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The Long-term stability study data is conducted at 25°C ±2°C / 65% ± 5% RH for 36 months. Now the firm has submitted 18 months long term stability studies data as per Zone IVb conditions, detailed as under: **Batch# / Initial date / Duration** 201007 / 07-2020 / 18 months 201008 / 07-2020 / 18 months 201009 / 07-2020 / 18 months Firm has claimed 36 months shelf life on basis of above submitted data.
	Details of diluent:	**Composition:** Water for injection **Container closure:** 4ml Type I glass ampoule. **Manufacturer:** BIOMEDICA FOSCAMA Industria Chimico-Farmaceutica, S.p.A. Via Morolense n.87, 03013 Ferentino (FR) Italy. **Stability data:** Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The Long-term stability study data at 30°C ±2°C / 75% ± 5% RH has been submitted for 9 months only.

Evaluation by PEC[II]:
Clinical profile of the applied product is as under:

- **Therapeutic indications:**

Prophylaxis of neuropathy following chemotherapy treatment with cisplatin or analogue.

- **Pharmacotherapy category:**

Antidotes, ATC code: V03AB32

- **Dosage:**

The generally recommended daily dose of TAD in patients receiving cisplatin or analogue chemotherapy is 1.5 g / m2 (corresponding to 2.5 g) administered slowly intravenously.

- **Contraindications:**

Hypersensitivity to the active ingredient.

- **Pharmaceutical description:**

The drug substance is lyophilised in bulk form and then the bulk lyophilised powder is filled in glass vials.

Section#	Observation	Firm's response
1.5.2	Strength per unit is mentioned as Glutathione powder 600mg instead of Glutathione sodium.	Firm has corrected label claim without submission of fee.

1.5.6	Pharmacopoeial reference for applied product is stated as European Pharmacopeia, whereas European monograph is not available for applied product.	Firm has submitted statement from M/s Biomedica Foscama that the TAD 600mg/4ml powder and solvent for infusion state that the product is contained in packaging in compliance with European Pharmacopoeia.
3.2.P.2.6	Compatibility studies shall be performed with the diluent specified in individual label of the drug product.	Firm has submitted stability study of 8hours after reconstitutiton at 25±2ºC.
Diluent		
3.2.P.3.1	Details of the manufacturer of diluent shall be submitted.	
3.2.P.8.3	Long term stability studies data of diluent shall be submitted as per Zone Iva conditions till claimed shelf life i.e., 60 months.	Firm has submitted long term stability studies data of three batches as per Zone IVa for 18 months.

Decision of 320th meeting: Deferred for regulatory status of applied formulation in other reference regulatory authorities alongwith its indications, precautions, contra indications etc.

Frim's response:

1- Attached summary of product characteristics (SmPC) authorized by AIFA (Italian medicine agency) and that you can find on the official website of AIFA

Link: farmaci.agenziafarmaco.gov.it/bancadatifarmaci/farmaco?farmaco=027154

2- Being sold in Europe upon physician's prescription as TAD is registered in AIFA

a. Attached relevant section of Official Gazette of the Italian Republic in which decrees and laws are published which are effective from date of publication

b. Excerpt according to MHRA Section 9: Unlicensed medicines and sub section 9.3 "Expanded Access/ Compassionate Use/ Named patient supply programmes – Guidance notes"

c. Evidence of sales in Europe are attached (Delivery note and CMR – Transport documents)

d. Attached Periodic safety update reports (PSUR) submitted to AIFA, according to the European Union Reference Dates (EURD) list published on European Medicine Agency (EMA) website

3- Registration letters of TAD in countries, Kyrgyztan, O'zbekiston, Georgia, Azerbaijan, Kazakhstan, Laos, Philippines, China & Kuwait.

Proceedings & Decision: The Board was appriosed that in 291st meeting application of M/s Friends Pharma, Lahore was approved on basis of international reference of AIFA of Italy. The application was submitted on Form 5D, whereas the firm didn't submit product development and stability studies data as required by the Board for such applications.Moreover, reference was also forwarded to the pricing division for MRP fixation. The Board deliberated the matter in detail and decided as follows:

- **To refer the case to "Society of Oncology, Pakistan" for expert opinon regarding therapeutic use and need of applied formulation.**
- **To advise M/s Friends Pharma, Lahore to submit the stability studies data as per checklist approved by Board in its 293rd meeting and case will be considered by the Board after above opinion.**

1410. Tiofix Discair (Tiotropium Bromide anhydrous 18mcg) Inhalation Powder by M/s The Searle company Limited Karachi

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading

1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 13560 Dated 30-07-2019 (Rs. 100,000/- Dated 29-07-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s The Searle company Limited, 1st floor N.I.C.L Building Abbasi Shaheed Road off: Shahrah-E-Faisal Karachi-75530
	1.3.2	Name, address and contact details of Manufacturing site. M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	Drug Sale License M/s The Searle company Limited, suit no. 101 1st floor N.I.C Building Abbasi Shaheed Road Karachi Godowns address: F-2/Q SITE Karachi Drug License by way of Wholesale No. 0591 valid upto 03-05-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Tiofix Discair (Tiotropium Bromide anhydrous 18mcg) Inhalation Powder
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Tiotropium Bromide anhydrous 18mcg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Tiofix
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's (60 Doses)
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) antimuscarinic Bronchodilator
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration Oral Inhalation
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Tioflow 18mcg (Tiotropium as Bromide monohydrate 18mcg) Capsule of M/s The Searle Company Limited Karachi
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. SPIRIVA® 18 microgram, inhalation powder, hard capsule (Germany)
	1.5.10	Dosage form of applied drug Oral Inhaler
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted

	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity. M/s Teva Pharmaceutical Industries Ltd. Petah Tikva, Israel
	Original Legalized CoPP (Certificate#. 2018/3142) issued on 10-09-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Neutec Inhaler Ilac San. Ve Tic. A.S, Sakarya 1. Organize sanayo Bolgesi 2. Yol No.3 Artifiyes/ Sakarya/ Turkey valid until 10/09/2020. Original Notarized "Product specific Letter of Authorization" from M/s Neutec Inhaler Ilac San. Ve Tic. A.S,, Turkey declaring M/s The Searle company Limited authorized for registration approval. Dated 16.10.2018 Authorization valid for three years.	

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content Submitted
2.2 CTD Introduction Submitted
2.3 Quality Overall Summary (QOS)* Submitted

QUALITY OVERALL SUMMARY (QOS)

2.3	Drug substance (API) General information Submitted Manufacture Submitted Characterization Submitted Control of drug substance Submitted Reference standards Submitted Container closure system Submitted Stability Submitted
	Drug product Description and composition of the drug product Submitted Pharmaceutical development Submitted Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted Finished Pharmaceutical Product Submitted Manufacturing process development Submitted Container closure system Submitted Manufacture Submitted Control of excipients Submitted Control of drug product Submitted Reference standards and materials Submitted Container closure system Submitted Stability Submitted
2.4	Non-Clinical Overview Submitted
2.5	Clinical Overview Submitted
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Submitted
2.7	Clinical summary Submitted

MODULE 3: QUALITY
3.1 Table of Contents of Module 3 Submitted
3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Not submitted
	3.2.S.2.4	Control of Critical steps and intermediates Not Submitted

	3.2.S.2.5	Process Validation and/or Evaluation Not submitted
	3.2.S.2.6	Manufacturing process development not Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5		REFERENCE STANDARDS Submitted
3.2.S.6		CONTAINER CLOSURE SYSTEMS Submitted
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted

	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 24 months at 30±20C,75%RH and 6 months at 400C±75%RH for three batches.

Remarks of evaluator:
Applied formulation is Tiotropium Bromide Anhydrous while reference formulation is tiotropium bromide monohydrate.
Applied formulation is differ in Primary packaging material, secondary packaging material, unit dose and device design as well, clarify how it is generic of Spirivia that is reference product.
Same molecule Tioflow 18mcg (Tiotropium as Bromide monohydrate 18mcg) Capsule already registered in the name of importer M/s The Searle Company Limited Karachi
Decision of 293rd meeting: Deferred for submission of applied dosage form drug delivery data.

Firm's response:
Firm has submitted results of deleivered dose uniformity test, also comparative study with the reference product Spiriva Handihaler.

Remarks	Justification
Applied formulation is Tiotropium Bromide Anhydrous while reference formulation is Tiotropium Bromide Monohydrate.	Manufacturer Comments: Crystalline monohydrate of tiotropium bromide is protected with TR2004/02579T4-EP1326862B1-W00230928A1 in TR until 28.09.2021. Therefore, we use Tiotropium bromide anhydrous as active Substance. https:/ /data.epo.org/ publication-server/pdf-document?on=1326862&ki=B1&cc=EP&PD=20040915
Applied formulation is different in Primary packaging material, secondary packaging material, unit dose and device design as well, clarify how it is generic of Spirivia that is reference product.	Please note that primary packaging, secondary packaging material and device design can vary from innovator. According to USP Chapter <601> Aerosol, Nasal Sprays, metered dose inhaler and dry powder Inhaler – Specifies two tests for DPIs i.e, Delivered-Dose Uniformity & Aerodynamic Size Distribution. With reference to DRB 293 Meeting minutes, The equivalency of applied product with the reference product, in terms of –Target Delivered Dose, must be established. The compatibility of Tiofix Discair Inhalation Powder with reference product Spiriva Handihaler hard gelatin capsules must be established. Aerodynamic particle size Distribution (APSD) & Delivered Dose Uniformity (DDU) Tests were performed for both the innovator Spiriva (Tiotropium Bromide) and Tiofix (Tiotropium Bromide) to establish such equivalency. Comparable results were obtained and thus test product has in vitro bioequivalence to the reference Spiriva Handihaler Product. ***Documents Attached for Reference.***

	Same molecule Tioflow 18mcg (Tiotropium as Bromide monohydrate 18mcg) Capsule already registered in the name of importer M/s The Searle Company Limited Karachi	Tioflow 18mcg Capsule is locally registered in the name of The Searle Company Limited, F-319 SITE area Karachi, used traditionally while Tiofix (Finished Import) is under modern technique pre Dispensed device, so in order to increase patient compliance and maintain good Hygiene of patients Tiofix Discair 18mcg Inhalation powder is imported.

Decision of 323rd meeting: Approved with innovator's specification as per policy of inspections of manufacturer abroad. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

Case no. 05 Registration applications of Form 5 with stability studies data.

1411.	**Name and address of manufacturer / Applicant**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A Sundar Industrial Estate, Lahore**
	Brand Name + Dosage Form + Strength	DIBIAN 10mg Tablets
	Composition	Each Film Coated Tablet contains: Empagliflozin……..10 mg
	Diary No. Date of R& I & fee	Dy No. 437 17-11-2016 PKR 50,000/- 9-11-2016
	Pharmacological Group	Sodium Glucose Co-transporter 2 (SGLT2) Inhibitor
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Jardy tablet of M/s CCLpharmaceuticals.
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 25-03-2022.
	Remarks of the Evaluator	Case was previously deferred in 266th meeting for submission of stability data as per guidelines of 251st DRB meeting.

STABILITY STUDY DATA			
Drug	DIBIAN 10mg Tablets		
Name of Manufacturer	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A Sundar Industrial Estate, Lahore		
Manufacturer of API	M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., Chem & API's Industrial Zone, Linhai, Zheijiang , China.		
API Lot No.	EPG20190102		
Description of Pack (Container closure system)	Alu Alu Blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real time: 0, 3, 6 Months Accelerated: 0, 3, 6 Months		
Batch #	T-EM-01	T-EM-02	T-EM-03

Batch Size		2200 Tablets	2200 Tablets	2200 Tablets
Manufacturing Date		09-2019	09-2019	09-2019
1412.	**Name and address of manufacturer / Applicant**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A Sundar Industrial Estate, Lahore**		
	Brand Name + Dosage Form + Strength	DIBIAN 25mg Tablets		
	Composition	Each Film Coated Tablet contains: Empagliflozin……..25 mg		
	Diary No. Date of R& I & fee	Dy No. 443 17-11-2016 PKR 50,000/- 9-11-2016		
	Pharmacological Group	Sodium Glucose Co-transporter 2 (SGLT2) Inhibitor		
	Type of Form	Form 5D		
	Finished product Specifications	Manufacturer's specifications		
	Pack size & Demanded Price	As Per SRO		
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA		
	Me-too status (with strength and dosage form)	Jardy tablet of M/s CCLpharmaceuticals.		
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 25-03-2022.		
	Remarks of the Evaluator	Case was previously deferred in 266th meeting for submission of stability data as per guidelines of 251st DRB meeting.		

STABILITY STUDY DATA

Drug	DIBIAN 25mg Tablets		
Name of Manufacturer	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A Sundar Industrial Estate, Lahore		
Manufacturer of API	M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., Chem & API's Industrial Zone, Linhai, Zheijiang , China.		
API Lot No.	EPG20190102		
Description of Pack (Container closure system)	Alu Alu Blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real time: 0, 3, 6 Months Accelerated: 0, 3, 6 Months		
Batch #	T-EP-01	T-EP-02	T-EP-03
Batch Size	2200 Tablets	2200 Tablets	2200 Tablets
Manufacturing Date	09-2019	09-2019	09-2019

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Firm has now submitted the stability studies data as per checklist of 293rd meeting of Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to onsite inspection report of their product "Dexstom 30mg & 60mg capsule", which was conducted on 21st-22nd September, 2020 and was presented in 297th meeting of Registration Board held on 12-15th January, 2021
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	COAs of the API have been submitted. **Name of API** | **Batch #** Empagliflozin | EPG20190102

<table>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer</td><td>Submitted</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Submitted as per following ocnditions:
Accelerated: 40°C ± 2°C & 75±5%RH (6 months)
Real Time: 30°C ± 2°C & 65±5%RH (60 months)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate (ZJ20180032) issued by China Food & Drug Administration, valid upto 14-03-2023 for M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., China</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoices attested by AD I&E DRAP, Lahore, has been submitted.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th><th>Date of approval by DRAP</th></tr>
<tr><td>EPG20190102</td><td>30209775</td><td>262.5gm</td><td>20-05-2019</td></tr>
</table></td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted from M/s Genetics Pharmaceuticals</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator’s product tablet.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Submitted for three batches of each strength.</td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted CDP studies against the reference product of Eliquis tablet for each strength in three dissolution mediums of pH 1.2, 4.5 & 6.8, with acceptable f2 values.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>• The firm has submitted Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc.</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers
(real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
<tr><td></td><td colspan="2">Remarks of Evaluator:
Obs.: Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufcaturer.
Reply: Copy of GMP certificate (ZJ20180032) issued by China Food & Drug Administration, valid upto 14-03-2023 for M/s Zheijiang Hongyuan Pharmaceutical Co., Ltd., China.</td></tr>
<tr><td></td><td colspan="2">Decision: Approved with innovator’s specification.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.</td></tr>
</table>

	• **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1413.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A Sundar Industrial Estate, Lahore-Pakistan
	Brand Name +Dosage Form + Strength	Solovir Tablet 400mg
	Composition	Each Film Coated Tablet contains: Sofosbuvir …….... 400mg
	Diary No. Date of R& I & fee	PKR 20,000/- 14-11-2016
	Pharmacological Group	HCV Polymerase Inhibitors.
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	4x7's & as per SRO
	Approval status of product in Reference Regulator Authorities	Regulatory Agency: European Medicine Agency (EMA) **Brand Name:** Sovaldi 400mg Film coated Tablet **Manufacturer**: Gilead Sciences 280 Hight Holborn London, United Kingdom Product Information: 19/08/2022 Sovaldi - EMEA/H/C/002798 - N/0080
	Me-too status	Brand name(s) of drug available in Pakistan: 1)-CURE-C. 2) - SOFOHIL. 3) - SOFOMAC. 4) - SOFOS. Name(s) of company(s) manufacturing in Pakistan: 1) - GLOBAL PHARMA. 2) - HILTON. 3) - MACTER. 4) - GENIX.
	GMP status	Firm has submitted copy of cGMP certificate on the basis of inspection dated 25-03-2022
	Remarks of the Evaluator	Case was previously deferred in 266th meeting for submission of stability data as per guidelines of 251st DRB meeting.

STABILITY STUDY DATA

Drug	Solovir Tablet 400mg
Name of manufacturer	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A Sundar Industrial Estate, Lahore-Pakistan
Manufacturer of API	Anhui Yellen Pharmaceuticals Co., Ltd. No. 1 Pingshan Road, Lingbi Country, Anhui Province, China
API Lot No.	1706201
Description of Pack (Container closure system)	Alu-Alu Blister and a Unit Carton along with leaflet insert
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH

Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0,1,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-SF-01	T-SF-02	T-SF-03
Batch Size	2300 Tablets	2300 Tablets	2300 Tablets
Manufacturing Date	08-04-2019	10-04-2019	11-04-2019
Date of Initiation	16-04-2019	16-04-2019	16-04-2019
No. of Batches	03 Batches		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Firm has now submitted the stability studies data as per checklist of 293rd meeting of Registration Board.

Sr. No.	Documents to Be Provided	Status
15.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Dextom 30mg and 60mg", which was conducted on 21-09-2020 & 22-09-2020 and was presented in 297th meeting of Registration Board held on 12th to 15th January 2021.
16.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	COA's of API have been submitted Name of API: Sofosbuvir Batch No.: 170601
17.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical method for API has been submitted from relevant API manufacturers as well as from M/s Genetics Pharmaceuticals Pvt. Ltd.
18.	Stability study data of API from API manufacturer	Firm has submitted both Accelerated Stability Studies & long-term Stability Studies Reports of three batches as per Zone IV-A conditions from API manufacturers of API. Real time: 30°C ± 2° C / 65% ± 5% RH (24 months) Accelerated: 40°C ± 2°C / 75% ± 5% RH (6 months)
19.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Sofosbuvir: Firm has submitted copy of DML of manufacturer "Anhui Yellen Pharmaceuticals Co., Ltd.
20.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of ADC (Lahore) attested invoice provided for Sofosbuvir from M/S. Anhui Yellen Pharmaceuticals Co., Ltd. Invoice letter NoYL-20170505-1 invoice date 20170505. attested by AD DRAP I&E dated 01-06-2017. Quantity: 3.00Kg
21.	Protocols followed for conduction of stability study	Firm has submitted SOP for new product development & Stability protocol

22.	Method used for analysis of FPP	Drug product analytical method has been submitted
23.	Drug-excipients compatibility studies (where applicable)	Firm has not performed Drug-excipients compatibility studies and stated that the quantitative composition of their product is similar to that of innovator's product tablet.
24.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Drug Product (T-SF-01, T-SF-02, T-SF-03),
25.	Record of comparative dissolution data (where applicable)	Comparative dissolution Profile in 3 dissolution mediums of pH 1.2, 4.5 & 6.8 have been submitted against the innovator product of Sovaldi 400mg Film coated Tablet with acceptable values of f2.
26.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for both Accelerated & Long-term stability studies, including chromatograms, raw data sheets, COA and summary data sheets etc.
27.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail reports have been submitted.
28.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted photocopies of digital printouts of Real Time and Accelerated Conditions for complete stability studies of applied formulations.

Remarks of Evaluator:

Decision: Approved with innovator's specification..

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter**

1414.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A Sundar Industrial Estate, Lahore-Pakistan
	Brand Name +Dosage Form + Strength	Velvir Tablet 400mg / 100mg
	Composition	Each Film Coated Tablet contains: Sofosbuvir…….....400mg Velpatasvir as Co-povidone dispersion…….100mg
	Diary No. Date of R& I & fee	PKR 50,000/- 9-11-2016
	Pharmacological Group	Anti-Viral, HCV Polymerase Inhibitors.
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	4 x 7's & as per SRO
	Approval status of product in	Regulatory Agency: FDA

	Reference Regulator Authorities	**Brand Name:** Epclusa Film coated Tablet **Manufacturer**: Gilead Sciences 280 Hight Holborn London, United Kingdom
	Me-too status	Brand name: Hilvel Name of manufacturer: Hilton
	GMP status	Firm has submitted copy of cGMP certificate on the basis of inspection dated 25-03-2022
	Remarks of the Evaluator	Case was previously deferred in 266th meeting for submission of stability data as per guidelines of 251st DRB meeting.

STABILITY STUDY DATA

Drug	Velvir Tablet 400mg / 100mg		
Name of manufacturer	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A Sundar Industrial Estate, Lahore-Pakistan		
Manufacturer of API	**Velpatasvir co-povidone**: Anhui Yellen Pharmaceuticals Co., Ltd. No. 1 Pingshan Road, Lingbi Country, Anhui Province, China **Sofosbuvir**: Anhui Yellen Pharmaceuticals Co., Ltd. No. 1 Pingshan Road, Lingbi Country, Anhui Province, China		
API Lot No.	**Velpatasvir co-povidone:** 170602 **Sofosbuvir:** 170601		
Description of Pack (Container closure system)	Alu-Alu Blister and a Unit Carton along with leaflet insert		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0,1,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	T-SV-01	T-SV-02	T-SV-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	24-05-2019	25-05-2019	27-05-2019
Date of Initiation	01-06-2019	01-06-2019	01-06-2019
No. of Batches	03 Batches		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Firm has now submitted the stability studies data as per checklist of 293rd meeting of Registration Board.

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product "Dextom 30mg and 60mg capsule", which was conducted on 21-09-2020 & 22-09-2020 and was presented in 297th meeting of Registration Board held on 12th to 15th January 2021.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	COA's of both API have been submitted Name of API: Sofosbuvir Batch No.: 170601

		Name of API: Velpatasvir co-povidone Batch No.: 170602
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical method of both API's have been submitted from relevant API manufacturers as well as from M/s Genetics Pharmaceuticals Pvt. Ltd.
4.	Stability study data of API from API manufacturer	Firm has submitted both Accelerated Stability Studies & long-term Stability Studies Reports of three batches as per Zone IV-a conditions from API manufacturers of both APIs. Real time: 30°C ± 2° C / 65% ± 5% RH (24 months) Accelerated: 40°C ± 2°C / 75% ± 5% RH (6 months)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML of manufacturer "Anhui Yellen Pharmaceuticals Co., Ltd.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of ADC (Lahore) attested invoice provided for Sofosbuvir & Velpatasvir co-povidone from M/S. Anhui Yellen Pharmaceuticals Co., Ltd. Invoice letter NoYL-20170626 invoice date 26062017. attested by AD DRAP I&E dated 26-07-2017. **Sofosbuvir** **Quantity:** 3.00Kg **Batch No.:** 170601 **Velpatasvir co-povidone** **Quantity:** 0.75Kg **Batch No.:**170602
7.	Protocols followed for conduction of stability study	Firm has submitted SOP for new product development & Stability protocol
8.	Method used for analysis of FPP	Drug product analytical method has been submitted
9.	Drug-excipients compatibility studies (where applicable)	Firm has not performed Drug-excipients compatibility studies and stated that the quantitative composition of their product is similar to that of innovator's product tablet.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches of Drug Product (T-SV-01, T-SV-02, T-SV-03),
11.	Record of comparative dissolution data (where applicable)	Comparative dissolution Profile in 3 dissolution mediums of pH 1.2, 4.5 % 6.8 have been submitted against the innovator product of Epclusa 400mg / 100mg Film coated Tablet with acceptable values of f2.
12.	Data of 03 batches will be supported by attested respective documents like	Firm has submitted analytical record for both Accelerated & Long-term stability

	chromatograms, Raw data sheets, COA, summary data sheets etc.	studies, including chromatograms, raw data sheets, COA and summary data sheets etc.
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail reports have been submitted.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted photocopies of digital printouts of Real Time and Accelerated Conditions for complete stability studies of applied formulations.
Remarks of Evaluator:		
Decision: Approved with innovator's specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**		

Case no. 06 Registration applications under review:

1415.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 22-09-2020, wherein Dry powder injectable Carbapenem section is declared.
	Dy. No. and date of submission	Dy. No 31952 dated 22-11-2021
	Details of fee submitted	Rs.50,000/- dated 29-07-2020
	The proposed proprietary name / brand name	**Neutopem Sterile Dry Powder Injection 1gm**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate ……. 1gm
	Pharmaceutical form of applied drug	Dry powder Injection
	Route of administration	IV
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	**USP**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Penro Injection of M/s Bosch Pharma.
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 22-09-2020.
	Name and address of API manufacturer.	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 500mg Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India		
API Lot No.	1705205135 1705205096 1705203623		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	U6001	U6002	U7001
Batch Size	23800 vials	19680 vials	15360 vials

Manufacturing Date		07-2016	10-2016	10-2016
No. of Batches		03		
1097.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore**		
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan		
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 22-09-2020, wherein Dry powder injectable Carbapenem section is declared.		
	Dy. No. and date of submission	Dy.No 31951 dated 22-11-2021		
	Details of fee submitted	Rs.50,000/- dated 29-07-2020		
	The proposed proprietary name / brand name	**Neutopem Sterile Dry Powder Injection 500mg**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate ……. 500mg		
	Pharmaceutical form of applied drug	Dry powder Injection		
	Route of administration	IV		
	Pharmacotherapeutic Group of (API)	Antibiotic		
	Reference to Finished product specifications	**USP**		
	Proposed Pack size	1's		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	Approved by MHRA of UK		
	For generic drugs (me-too status)	Penro Injection of M/s Bosch Pharma.		
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 22-09-2020.		
	Name and address of API manufacturer.	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India		
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and		

		stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 500mg Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India		
API Lot No.	1705205135 1705205096 1705203623		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T6001	T6002	T6003
Batch Size	15870 vials	15870 vials	7870 vials

Manufacturing Date		07-2016	07-2016	10-2016
No. of Batches		03		
Documents submitted along with stability data.				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India issued by Drugs Control Administration, Telangana, India dated 02-03-2017		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice attested by AD DRAP I&E Lahore dated 19-10-2017 for the import of Meropenem 20Kg from M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India		
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	--		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted.		

Remarks of Evaluator[II]:

Section#	Shortcomings communicated	Firm's response
1.1	Differential fee for Rs. 25,000/- shall be submitted.	
1.5.3	As recommended by the USP monograph of "Meropenem for injection", the label claim shall state the quantity, in mg, of sodium (Na) in a given dosage of meropenem.	
1.6.5	Valid GMP certificate of the drug substance manufacturer shall be submitted.	
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required."	
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted".	
3.2.S.4.4	• Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification). • Submitted COA of drug substance from M.s Stallion does not reflect performance of test of	

	"sodium, carbonate content", sterility and endotoxin.	
3.2.S.5	Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug substance and drug product.	
3.2.P.1	• Sodium content in terms of sodium carbonate shall be declared in composition. • Details of reconstitution diluent shall be submitted.	
3.2.P.2.2.1	• Justify the proposed quantity of drug substance per unit vial since the drug substance contains meropenem blended with 15.10 to 16.50% w/w of sodium carbonate. • Submitted pharmaceutical equivalence report does not include test of sodium content.	
3.2.P.2.2.2	Justify the 5% age overage in the master formulation.	
3.2.P.2.6	Justification shall be submitted for the declared pH range of 5 – 7 in Compatibility study report.	
3.2.P.5.1	Submitted drug product specifications does not include test of Sodium content & Particulate matter.	
3.2.P.5.2	• Submitted limits and procedure for the test of "Content of Sodium" is not as per USP monograph. • Provide detailed method of sample stock solution preparation instead of mentioning the general statement "Constitute a container of Meropenem for Injection with a volume of water, corresponding to the quantity of solvent specified in the labelling". • Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	
3.2.P.5.3	Performance of Accuracy & precision parameter shall be submitted in Analytical method verification report studies.	
3.2.P.5.4	Drug product batch release COA does not include performance of test of "Content of Sodium", as recommended by USP monograph. Justification shall be submitted in this regard. Batch analysis COA of the relevant batches for which stability data has been submitted shall be provided.	
3.2.P.6	Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug product stability batches.	
3.2.P.8.3	• It is evident from the submitted raw data sheets that sample and standard concentrations for the performance of Assay test was not as recommended by USP monograph. Justification shall be submitted din this regard. • Provide details that which lot number of drug substance has been used in manufacturing of each stability batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point, since the submitted	

	chromatograms and analytical reports are without any proper sequence. • Provide Reference of previous approval of applications with stability study data of the firm (if any) • Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). • Submitted stability study summary sheets reflect that tests of particulate matter, sterility tests, endotoxin test & Content of sodium have not been performed during stability studies. • Complete batch manufacturing record of the stability batches of drug product shall be submitted.	

Proceedings & Decision: Registration Board was apprised that the applied formulation has already been approved in 312th meeting of Registration Board for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, wherein following submission had also been made by the firm and above mentioned points have been addressed and responded:

1. **Evidence for purchase of atomic absorption spectrophotometer in the form of purchase order dated 14-06-2021, deliver challan dated 19-06-2021 & invoice No. 06/3029 dated 18-06-2021.**
2. **Installation and operational qualification reports of atomic absorption spectrophotometer**
3. **Analysis report of Sodium Content in Mopen (Meropenem) Injection by M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**

On basis of above cited reference Registration Board decided to approve applications of "Neutopenem Sterile Dry Powder 1g Injection" & "Neutopenem Sterile Dry Powder 500mg Injection". Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**
- **Firm shall submit differential fee fo Rs. 25,000/- for each strength for contract manufcaturing application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

1416.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 22-09-2020, wherein Dry powder injectable Carbapenem section is declared.
	Dy. No. and date of submission	Dy.No 29428 dated 28-10-2021
	Details of fee submitted	Rs.50,000/- dated 25-06-2020
	The proposed proprietary name / brand name	**Penem Sterile Dry Powder 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate …… 500mg
	Pharmaceutical form of applied drug	Dry powder Injection
	Route of administration	IV
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	**USP**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Penro Injection of M/s Bosch Pharma.
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 22-09-2020.
	Name and address of API manufacturer.	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 500mg Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India		
API Lot No.	1705205135 1705205096 1705203623		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	U6001	U6002	U7001
Batch Size	23800 vials	19680 vials	15360 vials
Manufacturing Date	07-2016	10-2016	10-2016
No. of Batches	03		

1417.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals Pvt Ltd. 581-Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 22-09-2020, wherein Dry powder injectable Carbapenem section is declared.
	Dy. No. and date of submission	Dy. No 31950 dated 22-11-2021
	Details of fee submitted	Rs.50,000/- dated 25-06-2020
	The proposed proprietary name / brand name	**Penem Sterile Dry Powder 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate …… 500mg
	Pharmaceutical form of applied drug	Dry powder Injection
	Route of administration	IV
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	**USP**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Penro Injection of M/s Bosch Pharma.
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 22-09-2020.
	Name and address of API manufacturer.	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Meronem 500mg Injection of Pfizer Pakistan Ltd.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India		
API Lot No.	1705205135 1705205096 1705203623		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T6001	T6002	T6003
Batch Size	15870 vials	15870 vials	7870 vials
Manufacturing Date	07-2016	07-2016	10-2016
No. of Batches	03		

Documents submitted along with stability data.

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India issued by Drugs Control Administration, Telangana, India valid up to 13-10-2017.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice attested by AD DRAP I&E Lahore dated 19-10-2017 for the import of Meropenem 20Kg from M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India

4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	--
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted.

Remarks of Evaluator[II]:

Section#	Shortcomings communicated	Firm's response
1.1	Differential fee for Rs. 25,000/- shall be submitted.	
1.5.3	As recommended by the USP monograph of "Meropenem for injection", the label claim shall state the quantity, in mg, of sodium (Na) in a given dosage of meropenem.	
1.6.5	Valid GMP certificate of the drug substance manufacturer shall be submitted.	
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required."	
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted".	
3.2.S.4.4	• Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (e.g. results not tested according to the proposed specification). • Submitted COA of drug substance from M.s Stallion does not reflect performance of test of "sodium, carbonate content", sterility and endotoxin.	
3.2.S.5	Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug substance and drug product.	
3.2.P.1	• Sodium content in terms of sodium carbonate shall be declared in composition. • Details of reconstitution diluent shall be submitted.	
3.2.P.2.2.1	• Justify the proposed quantity of drug substance per unit vial since the drug substance contains meropenem blended with 15.10 to 16.50% w/w of sodium carbonate. • Submitted pharmaceutical equivalence report does not include test of sodium content.	
3.2.P.2.2.2	Justify the 5% age overage in the master formulation.	
3.2.P.2.6	Justification shall be submitted for the declared pH range of 5 – 7 in Compatibility study report.	

3.2.P.5.1	Submitted drug product specifications does not include test of Sodium content & Particulate matter.	
3.2.P.5.2	• Submitted limits and procedure for the test of "Content of Sodium" is not as per USP monograph. • Provide detailed method of sample stock solution preparation instead of mentioning the general statement "Constitute a container of Meropenem for Injection with a volume of water, corresponding to the quantity of solvent specified in the labelling". • Justify why the formula for calculation of assay contents of meropenem is different than that mentioned in USP monograph.	
3.2.P.5.3	Performance of Accuracy & precision parameter shall be submitted in Analytical method verification report studies.	
3.2.P.5.4	Drug product batch release COA does not include performance of test of "Content of Sodium", as recommended by USP monograph. Justification shall be submitted in this regard. Batch analysis COA of the relevant batches for which stability data has been submitted shall be provided.	
3.2.P.6	Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of drug product stability batches.	
3.2.P.8.3	• It is evident from the submitted raw data sheets that sample and standard concentrations for the performance of Assay test was not as recommended by USP monograph. Justification shall be submitted din this regard. • Provide details that which lot number of drug substance has been used in manufacturing of each stability batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point, since the submitted chromatograms and analytical reports are without any proper sequence. • Provide Reference of previous approval of applications with stability study data of the firm (if any) • Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). • Submitted stability study summary sheets reflect that tests of particulate matter, sterility tests, endotoxin test & Content of sodium have not been performed during stability studies. • Complete batch manufacturing record of the stability batches of drug product shall be submitted.	

Proceedings & Decision: Registration Board was apprised that the applied formulation has already been approved in 312th meeting of Registration Board for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant,

wherein following submission had also been made by the firm and above mentioned points have been addressed and responded:

1. **Evidence for purchase of atomic absorption spectrophotometer in the form of purchase order dated 14-06-2021, deliver challan dated 19-06-2021 & invoice No. 06/3029 dated 18-06-2021.**
2. **Installation and operational qualification reports of atomic absorption spectrophotometer**
3. **Analysis report of Sodium Content in Mopen (Meropenem) Injection by M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**

On basis of above cited reference Registration Board decided to approve applications of "Penem Sterile Dry Powder 1g Injection" & "Penem Sterile Dry Powder 500mg Injection". Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore wherein panel shall also review the testing of drug substance and drug product of applied formulation as per pharmacopoeial requirements.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**
- **Firm shall submit differential fee fo Rs. 25,000/- for each strength for contract manufcaturing application as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

1418.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on basis of inspection conducted on 31-12-2018 & 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Capsule cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32858 dated 02-12-2021
	Details of fee submitted	Rs.50,000/- dated 05-11-2020
	The proposed proprietary name / brand name	**C-FIX 200 mg Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Cefixime trihydrate as cefixime …..200 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Third-Generation Cephalosporin ANTIBIOTIC CEPHALOSPORIN

	Reference to Finished product specifications	JP specification
	Proposed Pack size	1x10's
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Cefixima normon 200mg capsules M/s Laboratories Normon, S.A., Spain approved by AEMPS of Spain
	For generic drugs (me-too status)	Maxpan capsule 200mg/ M/s Indus pharma
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd C-7/1, North Western Industrial Zone, Port Qasim Karachi – 75020, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Cebosh Capsule 200mg" of M/s Bosch Pharmaceutical (Pvt.) Ltd. has been submitted.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.
STABILITY STUDY DATA		

Manufacturer of APIs	M/s Saakh Pharma (Pvt) Ltd C-7/1, North Western Industrial Zone, Port Qasim Karachi – 75020, Pakistan		
API Lot No.	19CF10020		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	50,000 Capsule	50,000 Capsule	50,000 Capsule
Manufacturing Date	09/2018	09/2018	09/2018

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued on basis of inspection conducted on 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (CFX/2019/2372) for procurement of 20Kg of Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

Section	Observation	Firm's response
1.1	Submit differential fee of Rs. 25,000/- for each strength as per Notification No. F.7-11f2012-B&A/DRAP dated 07th May, 2021.	
1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Neutro Pharma shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. • Commercial invoice form M/s Saakh Pharma declare Cefixime of micronized grade whereas	

	the COA of drug substance from M/s Neutro pharma declare it of Compacted grade. Clarification shall besubmitted in this regard.		
3.2.S.7.3	• It is not evident form the submitted stability reports that whether the stability data is for Cefixime micronized grade or Cefixime compacted grade.		
3.2.P.1	• List of all components of the dosage form, and their amount on a per unit basis shall be submitted.		
3.2.P.2.2.1	• Justification shall be submitted for performing CDP studies with one sampling time point only.		
3.2.P.5.1	• Justify the drug product specifications in which the assay and dissolution test analytical method and acceptance criteria is completely different from JP monograph as well as innovator's product. • Justification shall be submitted for proposed limits of Disntegration test.		
3.2.P.5.3	Analytical method verification studies shall be submitted as per the monograph of cefixime capsule approved by registration board in its 313rd meeting.		
3.2.P.8.3	• Complete raw data sheets wherein detail of sample & standard solution preparation along with calculation formula shall be submitted. • Justification shall be submitted for not performing dissolution test during stability studies. • Complete Batch manufacturing records for the stability batches shall be submitted. • Submitted stability studies reveal that test for Assay has not been performed as per the JP monograph of Cefixime capsule or the monograph approved by registration board in its 313rd meeting. Clarification shall be submitted in this regard.		

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

1419.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on basis of inspection conducted on 31-12-2018 & 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Capsule cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy.No 32859 dated 02-12-2021
	Details of fee submitted	Rs.50,000/- dated 29-12-2020
	The proposed proprietary name / brand name	**C-Fix 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Cefixime as Trihydrate ……. 200mg
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	ANTIBIOTIC CEPHALOSPORIN Third-Generation Cephalosporin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	1x30ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	M/s Generics (UK) **Ltd t/a Mylan** Approved by MHRA of UK
	For generic drugs (me-too status)	Cefspan 200mg suspension Barrett Hodgson Pharma /**Pakistan**
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd C-7/1, North Western Industrial Zone, Port Qasim Karachi – 75020, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Fix suspensione" has been submitted.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.
STABILITY STUDY DATA		

Manufacturer of APIs	M/s Saakh Pharma (Pvt) Ltd C-7/1, North Western Industrial Zone, Port Qasim Karachi – 75020, Pakistan		
API Lot No.	19CF10020		
Description of Pack (Container closure system)	Glass bottle, PP cap, Label Unit carton and leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	2000 Pack	2500 Pack	2000 Pack
Manufacturing Date	6/19	6/19	6/19

1420.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on basis of inspection conducted on 31-12-2018 & 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Capsule cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32860 dated 02-12-2021
	Details of fee submitted	Rs.50,000/- dated 29-12-2020
	The proposed proprietary name / brand name	**C-Fix 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime trihydrate as cefixime…..100 mg
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	ANTIBIOTIC CEPHALOSPORIN Third-Generation Cephalosporin
	Reference to Finished product specifications	USP specification
	Proposed Pack size	1x30ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Cefspan 100mg suspension Barrett Hodgson Pharma /**Pakistan**
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd C-7/1, North Western Industrial Zone, Port Qasim Karachi – 75020, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Cebosh Capsule 200mg" of M/s Bosch Pharmaceutical (Pvt.) Ltd. has been submitted.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.

STABILITY STUDY DATA			
Manufacturer of APIs	M/s Saakh Pharma (Pvt) Ltd C-7/1, North Western Industrial Zone, Port Qasim Karachi – 75020, Pakistan		
API Lot No.	19CF10020		
Description of Pack (Container closure system)	Alu-Alu foil		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	2300 pack	2000 Pack	2100 Pack
Manufacturing Date	6/19	6/19	6/19

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued on basis of inspection conducted on 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (CFX/2019/2372) for procurement of 20Kg of Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

Section	Observation	Firm's response
1.1	Submit differential fee of Rs. 25,000/- for each strength as per Notification No. F.7-11f2012-B&A/DRAP dated 07th May, 2021.	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Neutro Pharma shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. • Commercial invoice form M/s Saakh Pharma declare Cefixime of micronized grade whereas the COA of drug substance from M/s Neutro pharma declare it of Compacted grade. Clarification shall besubmitted in this regard.	
3.2.S.7.3	• It is not evident form the submitted stability reports that whether the stability data is for Cefixime micronized grade or Cefixime compacted grade.	
3.2.P.1	• List of all components of the dosage form, and their amount on a per unit basis shall be submitted. • Details of the diluent required for reconstituition of suspension shall be submitted.	
3.2.P.2.6	• Compatibility study with the reconstitution diluent shall be submitted.	
3.2.P.5.1	• Submitted analytical procedure fro Assay test does not include detailsfor standard solution preparation. • Sample solution preparation method shall be elaborated for amount of diluent used for reconstitution of suspension. • Justification shall be submitted for not includeing test of preservative effectiveness and preservative content in the drug product specifications.	
3.2.P.8.3	• Details of batch# and batch size are different between data submitted in section 3.2.P.5.4, 3.2.P.8.1 & 3.2.P.8.3. Clarification shall be submitted in this regard. • Complete raw data sheets wherein detail of sample & standard solution preparation	

	along with calculation formula shall be submitted. • Justification shall be submitted for not performing test of preservative effectiveness and preservative content during stability studies. • Complete Batch manufacturing records for the stability batches shall be submitted. • In-use stability studies data for the reconstitutted suuspension shall be submitted.	

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

1421.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on basis of inspection conducted on 31-12-2018 & 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 33170 dated 21-12-2021
	Details of fee submitted	Rs.50,000/- dated 10-03-2021
	The proposed proprietary name / brand name	**Ramdol 100mg Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Contains: Tramadol HCl …… 100mg
	Pharmaceutical form of applied drug	Liquid injection
	Pharmacotherapeutic Group of (API)	Opiod analgesic
	Reference to Finished product specifications	Neutro's specification
	Proposed Pack size	5's
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Votadol 100mg Injection of M/s Horizon
	Name and address of API manufacturer.	M/s Virupaksha Organics Ltd., Survey No. 10G gaddapotharam Village, Jinnaram Mandal, Medak District, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

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

STABILITY STUDY DATA			
Manufacturer of APIs	M/s Virupaksha Organics Ltd., Survey No. 10G gaddapotharam Village, Jinnaram Mandal, Medak District, Telangana, India.		
API Lot No.	LDTM/0550719		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	5000 ampoules	5000 ampoules	5000 ampoules
Manufacturing Date	05-2020	05-2020	05-2020

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (BEXP-1718-429) attested by AD I&E DRAP Lahore dated 07-03-2018 for import of 20Kg of Cefotaxime sodium.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

Section	Observation	Firm's response
1.1	Submit differential fee of Rs. 25,000/- for each strength as per Notification No. F.7-11f2012-B&A/DRAP dated 07th May, 2021.	
1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Neutro Pharma shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.P.2.2.1	The limits of pH test are different from that specified in USP monograph.	
3.2.P.3.5	Process validation protocol shall be submitted.	
3.2.P.5.2	Submitted drug analytical procedure describes UV spectrophotometric method for Assay test. Justification shall be submitted for not adopting HPLC method for the performance of Assay test.	
3.2.P.5.3	Analytical method verification studies have been submitted for the HPLC method whereas section 3.2.P.5.2 describes UV method. Justificaton shall be submitted in this regard.	
3.2.P.8.3	• Submitted analytical record of stability studies for Assay test is different from the analytical method proposed in section 3.2.P.5.2. • Complete raw data sheets wherein detail of sample & standard solution preparation along with calculation formula shall be submitted. • Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Complete Batch manufacturing records for the stability batches shall be submitted. • Clarification shall be submitted whether submitted stability data is of trial batches or commercial batches. • Microbiological Reports for sterility testing & Bacterial Endotoxin testing. • Documents confirming import of drug substance with approval of DRAP shall be submitted.	

	• Valid GMP certificate of drug substance manufcaturer shall be submitted. • Details of the minimum handling capacity of the compounding vessel used for manufacturing of stability batches shall be submitted.	

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

1422.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on basis of inspection conducted on 31-12-2018 & 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34004 dated 29-12-2021
	Details of fee submitted	Rs.50,000/- dated 10-02-2020
	The proposed proprietary name / brand name	**C-Tac 500mg IM/IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefotaxime as Sodium…500mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Antibacterial cephalsporin
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1's x 100ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Claforan of M/s Sanofi Aventis Pakistan
	Name and address of API manufacturer.	M/s Kopran Research Labs. Ltd., Mahad Dist., Maharashtra State. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

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

STABILITY STUDY DATA

Manufacturer of APIs	M/s Kopran Research Labs. Ltd., Mahad Dist., Maharashtra State. India		
API Lot No.	DC-004-2004008		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	004	005	006
Batch Size	7000 vials	7000 vials	7000 vials
Manufacturing Date	03-19	03-2019	03-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (BEXP-1718-429) attested by AD I&E DRAP Lahore dated 07-03-2018 for import of 20Kg of Cefotaxime sodium.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

Section	Observation	Firm's response
1.1	Submit differential fee of Rs. 25,000/- for each strength as per Notification No. F.7-11f2012-B&A/DRAP dated 07th May, 2021.	
1.6.5	Valid GMP certificate issued by the relevant regulatory authority shall be submitted for the drug substance manufacturer.	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Neutro Pharma shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. • Submitted COA of drug substance from M/s Neutro does not include test if sterility. • Evidence of availability of HPLC system equipped with Auto-sampler able to maintain temperature of 4°C, as required by USP monograph, shall be submitted.	
3.2.P.1	Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) for the diluent which is to be provided along with the applied drug.	
3.2.P.2.2	The section declares "an overage 0.2% of Cefotaxime sodium is added to compensate inactive moiety." Scientific justification shall be submitted for this declaration.	
3.2.P.2.2.1	The limits of pH test are different from that specified in USP monograph.	
3.2.P.2.6	Compatibility studies shall be performed as per the instructions provided in individual label of the drug product.	
3.2.P.5	• Justification shall be submitted for the limit of average fill weight per vial. • Drug product specifications have been referred to as per USP, whereas analytical procedure for Assay method is not as per the USP monograph of "Cefotaxime for injection." • Analytical method verification studies have	

	not been performed as per USP monograph	
3.2.P.5.2	Submitted drug analytical procedure describes UV spectrophotometric method for Assay test. Justification shall be submitted for not adopting HPLC method for the performance of Assay test.	
3.2.P.5.3	Performance of specificity parameter has not been done in the analytical method validation studies.	
3.2.P.8.3	• Details of batch# and batch size are different between data submitted in section 3.2.P.5.4, 3.2.P.8.1 & 3.2.P.8.3. Clarification shall be submitted in this regard. • Submitted analytical record of stability studies for Assay reflect that in contradiction to the specification claimed in section 3.2.P.5.1, Assay test has not been performed as per the USP monograph of "Cefotaxime for injection". • Complete raw data sheets wherein detail of sample & standard solution preparation along with calculation formula shall be submitted. • Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Complete Batch manufacturing records for the stability batches shall be submitted. • Clarification shall be submitted whether submitted stability data is of trial batches or commercial batches. • Microbiological Reports for sterility testing & Bacterial Endotoxin testing.	

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

1423.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on basis of inspection conducted on 31-12-2018 & 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34002 dated 29-12-2021
	Details of fee submitted	Rs.50,000/- dated 29-12-2020

	The proposed proprietary name / brand name	**Radilev 500mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Levofloxacin as Hemihydrate …..… 500mg
	Pharmaceutical form of applied drug	Parenteral (Injectable)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1's x 100ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Effiflox infusuion of M/s Sami
	Name and address of API manufacturer.	M/s Zheijiang East Asia Pharmaceutical Co., Ltd., economic development zone of Sanmen County, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH..
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Livlong infusion" of M/s English Pharma has been submitted.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.
STABILITY STUDY DATA		

Manufacturer of APIs	M/s Zheijiang East Asia Pharmaceutical Co., Ltd., economic development zone of Sanmen County, Zhejiang, P.R. China.		
API Lot No.	DC-004-2004008		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	4000 vials	4000 vials	4000 vials
Manufacturing Date	06-19	06-2019	06-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate# ZJ20160079 issued BY CFDA till 15-08-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (LEV200729-L) attested by AD I&E DRAP Lahore dated 05-08-2020 for import of 500Kg of Levofloxacin hemihydrate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

Section	Observation	Firm's response
1.1	Submit differential fee of Rs. 25,000/- as per Notification No. F.7-11f2012-B&A/DRAP dated 07th May, 2021.	
1.5.9	Evidence of approval of applied product of "Levofloxacin in 5% dextrose infusion" by reference regulatory authorities in the proposed container closure system of glass vial, shall be submitted.	
1.6.5	Valid GMP certificate issued by the relevant regulatory authprity shall be submitted for the drug substance manufacturer.	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Neutro Pharma shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.P.2.2.2	Scientific justification shall be submitted for 5% overage.	

3.2.P.3.3	Submitted manufacturing method does not include step of terminal sterilisation. Justification shall be submitted in this regard.		
3.2.P.5.2	Submitted drug analytical procedure describes UV spectrophotometric method for Assay test. Justification shall be submitted for not adopting HPLC method for the performanc of Assay test.		
3.2.P.5.3	Performance of specificity parameter has not been done in the analytical method validation studies.		
3.2.P.8.3	• Complete raw data sheets wherein detail of sample & standard solution preparation along with calculation formula shall be submitted. • Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Complete Batch manufacturing records for the stability batches shall be submitted. • Clarification shall be submitted whether submitted stability data is of trial batches or commercial batches. • Microbiological Reports for sterility testing & Bacterial Endotoxin testing.		

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

1424.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm (manufcaturer)	GMP certificate issued on basis of inspection conducted on 31-12-2018 & 28-02-2019.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Neutro Pharma, declaring the availability of Injectable general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32857 dated 02-12-2021
	Details of fee submitted	Rs.50,000/- dated 10-02-2020
	The proposed proprietary name / brand name	**Mopla 1g/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml infusion contains: Paracetamol …….. 1gm
	Pharmaceutical form of applied drug	Parenteral (Injectable)
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's specification

	Proposed Pack size	1's x 100ml
	Proposed unit price	As per DRAP policy.
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Falgan infusuion of M/s Bosch
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH..
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Provas infusion" of M/s Sami has been submitted.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.

STABILITY STUDY DATA			
Manufacturer of APIs	M/s Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone Port Qasim Karachi.		
API Lot No.	18GN60018		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003

Batch Size	4000 vials	4000 vials	4000 vials
Manufacturing Date	06-19	06-2019	06-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued on basis of inspection conducted on 18-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	--

Remarks of Evaluator:

Section	Observation	Firm's response
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by M/s Neutro Pharma shall be submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.S.4.4	Provided drug substance analysis method from M/s Saakh pharma declare Assay method as per USP monograph, whereas COA of drug substance from M/s Neutreo Pharma declare it as of BP standard. Justification shall be submitted in this regard.	
3.2.S.7	Accelerated stability studies have been submitted till 12-month time point. Clarification shall be submitted in this regard. Same stability data has been submitted for both accelerated & long term conditions for batch# 18GN60002.	
3.2.P.2.1	• Role of "Sodium metabisulfite" as preservative shall be justified in the proposed formulation. • Scientific justification is required for not using antioxidant in the applied formulation since the innovator brand used cysteine as an antioxidant because paracetamol is susceptible to degradation by oxidation.	
3.2.P.2.2.2	The section declares "an overage 2.5% of paracetamol is added to compensate inactive moiety." Scientific justification shall be submitted for this declaration.	
3.2.P.3.2	Justify the proposed quantity of 1025mg per vial of Paracetamol against the label claim of 1000mg per vial.	

3.2.P.5.1	Scientific justification is required for not performing test of osmolality while batch release of trial batches of drug product, since the test has included in drug product specification of innovator brand. Justification shall be submitted for the limits of pH test.		
3.2.P.5.2	Submitted drug analytical procedure describes Assay test for Paracetamol tablet instead of Paracetamol infusion.		
3.2.P.5.3	Performance of specificity parameter has not been done in the analytical method validation studies.		
3.2.P.8.3	• Details of batch# and batch size are different between data submitted in section 3.2.P.5.4, 3.2.P.8.1 & 3.2.P.8.3. Clarification shall be submitted in this regard. • Limits of pH test are different between those mentioned in stability sheet and that declared in the drug product specifications. • Limits of bacterial endotoxin test are different between those mentioned in stability sheet and that declared in the drug product specifications. • Complete raw data sheets wherein detail of sample & standard solution preparation along with calculation formula shall be submitted. • Documents confirming procurement of drug substance shall be submitted. • Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Complete Batch manufacturing records for the stability batches shall be submitted. • Clarification shall be submitted whether submitted stability data is of trial batches or commercial batches. • Microbiological Reports for sterility testing & Bacterial Endotoxin testing.		

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

1425.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 23-04-2019, wherein Liquid Ampoule section is declared.
	Dy. No. and date of submission	Dy. No 27309 dated 04-10-2021
	Details of fee submitted	Rs.50,000/- dated 07-04-2021
	The proposed proprietary name / brand name	**Allosetron 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Contains: Ondansetron as HCl Dihydrate …… 8mg
	Pharmaceutical form of applied drug	Liquid Injection
	Route of administration	IV/IM
	Pharmacotherapeutic Group of (API)	5-HT3 antagonist
	Reference to Finished product specifications	**USP**
	Proposed Pack size	1's
	Proposed unit price	As per Policy
	The status in reference regulatory authorities	Setronon injection 8mg/4ml by M/s Teva Pharmaceutical Works Private Limited Company, H-2100 Gödöllo, Tánasics Mihaly. Út 82. Hungary, MHRA Approved.
	For generic drugs (me-too status)	ONSET Injection 8mg/4ml by M/s Pharmedic Laboratories (Pvt) Ltd. Reg. No. 025996
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 23-04-2019.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63 KSSIDC INDUSTRIAL ESTATE, Doddabullapur, banghaluru rural District-561203, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $25^{O} \pm 2^{O}$ C /60% ± 5% RH for 6 months. The real time stability data is conducted at $5^{O}C \pm 3^{O}$ C.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence studies against the Onset injection of M/s Pharmdeic.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63 KSSIDC INDUSTRIAL ESTATE, Doddabullapur, banghaluru rural District-561203, India		
API Lot No.	AOND-21003		
Description of Pack (Container closure system)	Amber glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 09 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	A-762	A-763	A-807
Batch Size	103.73Ltrs	10,000 Packs	50,000packs
Manufacturing Date	11-2019	11-2019	02-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Valid GMP certificate issued by Drug control department, govt. of Karnataka valid upto 05-02-2022 has been submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#CFC6503/21-22) approved by AD DRAP I&E Islamabad dated 23-04-2021 for the import of 2 Kg of Ondansetron HCl.
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes

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

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.S.4.4	COAs of relevant batches of drug substance used for the formulation of submitted stability batches of drug product, shall be submitted from both drug substance manufacturer and drug product manufacturer.	
3.2.S.5	Submitted COA of working standard declare its validity as 15-03-2019, whereas drug substance analysis has been performed subsequent to this date.	
3.2.S.6	Justify the use of "polyethylene bags" as primary container closure, for the injectable grade drug substance.	
3.2.S.7	Submitted summary sheets for the long term stability studies does not declare the temperature humidity conditions.	
3.2.P.1	Proposed quantity of 10.07mg Ondansetron HCl dehydrate per dosage unit shall be justified.	
3.2.P.2.2.3	The section declares pH between 4.6-4.7, which is not as per USP monograph.	
3.2.P.2.3	The section declares manufacturing process for a dry powder injection whereas applied formulation is a liquid injection.	
3.2.P.2.6	A tale declaring study for appearance after reconstitution has been submitted. Justification shall be submitted in this regard.	
3.2.P.3.3	Submitted manufacturing procedure neither includes step of terminal sterilization nor the aseptic filtration prior to the ampoule filling. Justification shall be submitted regarding how the sterility of product is ensured.	
3.2.P.3.4	Control of critical steps and intermediates does not include any terminal sterilization process.	
3.2.P.3.5	Submitted process validation report neither include any process of sterilization nor any test of sterility at any stage of manufacturing.	
3.2.P.5.1	• Formal controlled document for the drug product specifications and analytical procedure shale submitted form /s Bio-Labs.	
3.2.P.5.3	Concentration of sample solution declared in the analytical procedure is not as per USP monograph. Performance of precision parameter has not been included n the AMV report.	

	3.2.P.8.3	• Submit import documents attested by AD DRAP I&E, confirming import of relevant batches of drug substance used for the formulation of submitted stability batches of drug product. • Complete batch manufacturing record for the stability batches of drug product shall be submitted.	

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

1426.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 23-04-2019, wherein Liquid Ampoule section is declared.
	Dy. No. and date of submission	Dy.No 27282 dated 01-10-2021
	Details of fee submitted	Rs.50,000/- dated 07-04-2021
	The proposed proprietary name / brand name	**Allo-D Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Cholecalciferol ……. 5mg
	Pharmaceutical form of applied drug	Liquid Injection
	Route of administration	Oral/IM
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	**Innovator specifications**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	-----
	For generic drugs (me-too status)	Sunny D Injection of M/s Scotmann Pharma (Reg.#063450)
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 23-04-2019.
	Name and address of API manufacturer.	M/s FERMENTA BIOTECH LIMITED, Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

		Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $25^{O} \pm 2^{O}$ C /60% ± 5% RH for 6 months. The real time stability data is conducted at $5^{O}C \pm 3^{O}$ C.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence studies against the Indrop-D injection.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s FERMENTA BIOTECH LIMITED, Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India
API Lot No.	B-1-51-M180903
Description of Pack (Container closure system)	Amber glass ampoule
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)

Batch No.	A-398	A-401	A-486
Batch Size	10,000 Packs	10,000 Packs	55 ltr
Manufacturing Date	02-2018	04-2018	08-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate (Certificate# 2062043) of M/s FERMENTA BIOTECH LIMITED. Plot no. Z-109-B 7 C, SEZ-II, DAHEJ, TAL-VAGRA, Dahej, dist. Bharuch, Gujarat State, India issued BY Food 7 Drugs Control Administration, Gujarat, India valid up to 17-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#RV2010020207) approved by AD DRAP I&E Islamabad dated 25-11-2020 for the import of Cholelcalciferol from M/s FERMENTA BIOTECH LIMITED. Plot no. Z-109-B 7 C, SEZ-II, DAHEJ, TAL-VAGRA, Dahej, dist. Bharuch, Gujarat State, India
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	--
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted.

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.5.9	Submitted evidence is of another reference product than for the formulation applied.	
2.3.R.1.1	Complete batch manufacturing record shall be submitted for the stability batches.	
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.3.3	Submitted manufacturing procedure neither includes step of terminal sterilization nor the aseptic filtration prior to the ampoule filling. Justification shall be submitted regarding how the sterility of product is ensured.	
3.2.P.3.4	Control of critical steps and intermediates does not include any sterilization process.	

3.2.P.3.5	Submitted process validation report neither include any process of sterilization nor any test of sterility at any stage of manufacturing.	
3.2.P.5.1	• Submitted drug product specifications does not include test of "Uniformity Of Dosage Units", "Foreign And Particulate Matter" & "Container content". • Justification shall be submitted for un-conventional Assay limits of "89.33% to 110.66%". • Test of sterility does not refer to any particular or general limits. • Submitted specification does not include test of endotoxin.	
3.2.P.5.3	Analytical method verification report of HPLC method of Assay test shall be submitted.	
3.2.P.5.4	Submitted COA does not include test of endotoxin, uniformity of dosage, container content. Submitted COA of batch# "A-978" declares manufacturing date as 11-2020, whereas the COA has been signed dated 19-03-2020.	
3.2.P.8.3	Submitted GMP certificate is of other drug substance manufacturer than that declared in section 1.6.5 & 3.2.S.2. Submitted commercial invoice is of date subsequent to the date of manufacturing of stability batches. Submitted commercial invoice is from other drug substance manufacturer than that declared in section 1.6.5 & 3.2.S.2. • Submitted COA of stability batches at all time points of stability studies does not include performance of tests of "Endotoxin test", "Uniformity Of Dosage Units", "Foreign And Particulate Matter" & "Container content". • Justification shall be submitted for performance of Assay analysis by "UV spectrophotometric method" during complete stability studies, whereas the drug substance manufacturer has applied HPLC method for drug substance analysis and also submitted drug product testing method in section 3.2.P.5.2 includes HPLC method for "Assay test".	

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

1427.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories Plot No. 121, Industrial Triangle, kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 23-04-2019, wherein Liquid Ampoule section is declared.
	Dy. No. and date of submission	Dy. No 27886 dated 08-10-2021
	Details of fee submitted	Rs.50,000/- dated 30-04-2021
	The proposed proprietary name / brand name	**Mega D Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Cholecalciferol ……. 5mg
	Pharmaceutical form of applied drug	Liquid Injection
	Route of administration	Oral/IM
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	**Innovator specifications**
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	-----
	For generic drugs (me-too status)	Sunny D Injection of M/s Scotmann Pharma (Reg.#063450)
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 23-04-2019.
	Name and address of API manufacturer.	M/s FERMENTA BIOTECH LIMITED, Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $25^{O} \pm 2^{O}$ C /60% ± 5% RH for 6 months. The real time stability data is conducted at $5^{O}C \pm 3^{O}$ C.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has performed pharmaceutical equivalence studies against the Indrop-D injection.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s FERMENTA BIOTECH LIMITED, Village Takoli, P.O. Nagwain, Dist. Mandi-175121, Himachal Pradesh, India		
API Lot No.	B-1-51-M180903		
Description of Pack (Container closure system)	Amber glass ampoule		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	A-398	A-401	A-486
Batch Size	10,000 Packs	10,000 Packs	55 ltr
Manufacturing Date	02-2018	04-2018	08-2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate (Certificate# 2062043) of M/s FERMENTA BIOTECH LIMITED. Plot no. Z-109-B 7 C, SEZ-II, DAHEJ, TAL-VAGRA, Dahej, dist. Bharuch, Gujarat State, India issued BY Food 7 Drugs Control Administration, Gujarat, India valid up to 17-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice (invoice#RV2010020207) approved by AD DRAP I&E Islamabad dated 25-11-2020 for the import of Cholelcalciferol from M/s FERMENTA BIOTECH LIMITED. Plot no. Z-109-B 7 C, SEZ-II, DAHEJ, TAL-VAGRA, Dahej, dist. Bharuch, Gujarat State, India
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	--

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

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.1	Differential fee for Rs. 25,000/- shall be submitted.	
1.5.9	Submitted evidence is of Vitamin D3 drops while applied formulation is of Injection.	
2.3.R.1.1	Complete batch manufacturing record shall be submitted for the stability batches.	
3.2.S.4.1	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	
3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.3.3	Submitted manufacturing procedure neither includes step of terminal sterilization nor the aseptic filtration prior to the ampoule filling. Justification shall be submitted regarding how the sterility of product is ensured.	
3.2.P.3.4	Control of critical steps and intermediates does not include any sterilization process.	
3.2.P.3.5	Submitted process validation report neither include any process of sterilization nor any test of sterility at any stage of manufacturing.	
3.2.P.5.1	• Submitted drug product specifications does not include test of "Uniformity Of Dosage Units", "Foreign And Particulate Matter" & "Container content". • Justification shall be submitted for un-conventional Assay limits of "89.33% to 110.66%". • Test of sterility does not refer to any particular or general limits. • Submitted specification does not include test of endotoxin.	
3.2.P.5.3	Analytical method verification report of HPLC method of Assay test shall be submitted.	
3.2.P.5.4	Submitted COA does not include test of endotoxin, uniformity of dosage, container content. Submitted COA of batch# "A-978" declares manufacturing date as 11-2020, whereas the COA has been signed dated 19-03-2020.	
3.2.P.8.3	Submitted GMP certificate is of other drug substance manufacturer than that declared in section 1.6.5 & 3.2.S.2.	

		Submitted commercial invoice is of date subsequent to the date of manufacturing of stability batches. Submitted commercial invoice is from other drug substance manufacturer than that declared in section 1.6.5 & 3.2.S.2. • Submitted COA of stability batches at all time points of stability studies does not include performance of tests of "Endotoxin test", "Uniformity Of Dosage Units", "Foreign And Particulate Matter" & "Container content". • Justification shall be submitted for performance of Assay analysis by "UV spectrophotometric method" during complete stability studies, whereas the drug substance manufacturer has applied HPLC method for drug substance analysis and also submitted drug product testing method in section 3.2.P.5.2 includes HPLC method for "Assay test".	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.			

Case no. 07 Request for Change in Registration Status of Products from M/s Getz Pharma (Pvt) Ltd, 29-30, Sector 27, Korangi Industrial Area, Karachi to M/s Getz Pharma (Pvt) Ltd, Plot No.01, Sector 25, Korangi Industrial Area, Karachi

M/s Getz Pharma (Pvt) Ltd, Plot No.01, Sector 25, Korangi Industrial Area, Karachi **(DML No. 000933)** has requested for change in registration status of following products from M/s Getz Pharma (Pvt) Ltd, 29-30, Sector 27, Korangi Industrial Area, Karachi **(DML No. 000284)** to their name. Detail is given as under:

I	II	III	IV
S. No.	**Reg. No.**	**Name of Drug(s)**	**Dy. No./ Date/Fee/ Initial date of registration/ Remarks of RRR Section regarding Renewal Status**
1.	045372	Cipesta Tablets 250mg Each film coated tablet contains: Ciprofloxacin (as Hydrochloride)……..250mg (USP Specifications)	Dy.No.20510 19-07-2022 Rs. 30,000/- (Invoice # 49086104 dated: 19-05-22) **DOR: 22-05-2007** Remarks of RRR Section: Renewal application within time with respect to change of approval for brand name dated 14-02-2013.
2.	045373	Cipesta Tablets 500mg Each film coated tablet contains: Ciprofloxacin (as Hydrochloride)……..500mg (USP Specifications)	Dy.No.20509 19-07-2022 Rs. 30,000/- (Invoice # 07394202849 dated: 19-05-22) **DOR: 22-05-2007** Remarks of RRR Section: Renewal application within time with respect to change of approval for brand name dated 14-02-2013.
3.	061344	Nebil Tablets 2.5mg Each tablet contains: Nebivolol as HCl……..2.5mg (Manufacturer's Specifications)	Dy.No. 24413/R&I 29-08-2022 Rs. 30,000/- (Invoice # 92207746868) **DOR: 28-04-2010** Remarks of RRR Section: Renewal application is submitted within time with respect to mentioned date of registration.
4.	061345	Nebil Tablets 5mg Each tablet contains: Nebivolol as HCl……..5mg (Manufacturer's Specifications)	Dy.No. 24414/R&I 29-08-2022 Rs. 30,000/- (Invoice # 6710942721) **DOR: 28-04-2010** Remarks of RRR Section: Renewal application is submitted within time with respect to mentioned date of registration.
5.	034838	Montiget 10mg Tablets Each film coated tablet contains:	Dy.No. 25560/R&I 09-09-2022

		Montelukast (as Sodium Salt)……10mg	Rs. 30,000/- (Invoice # 9445603675) **DOR: 20-12-2004** Remarks of RRR Section: Renewal application is submitted within time with respect to mentioned date of registration.
6.	047117	Moxiget 400mg Tablets Each tablet contains: Moxifloxacin (as Hydrochloride)…400mg (Manufacturer's Specification)	Dy.No. 25990/R&I 14-09-2022 Rs. 30,000/- (Invoice # 02292182925) **DOR: 18-09-2007** Remarks of RRR Section: Renewal application is submitted within time with respect to mentioned date of registration.
7.	103094	Diampa-M Tablet 5mg + 1000mg Each film coated tablet contains:- Empagliflozin …….. 5mg Metformin Hydrochloride…….. 1000mg (As per *Innovator's Specifications)	Dy.No. 27685/R&I **29-09-2022** Rs.30,000/- (Invoice# 80951026261) **DOR: 21-05-2020**
8.	093084	Diampa-M Tablet 12.5mg + 1000mg Each film coated tablet contains:- Empagliflozin …….. 12.5mg Metformin Hydrochloride…… ….. 1000mg (As per *Innovator's Specifications)	Dy.No. 27684/R&I **29-09-2022** Rs. 30,000/- (Invoice# 3442319097) **DOR: 16-01-2019**

Administrative Documents in the light of SOP approved by the Registration Board in its 283rd meeting

i. Copy of DML No. 000933 issued w.e.f. 25-05-2021

ii. Copy of Last Inspection report dated 17-11-2021.

iii. Approved sections verified from Licensing Division's letter for issuance of DML (dated 07th June, 2021):
- Tablet (General)
- Capsule (General)
- Dry Powder Suspension (General)

iv. NOC from M/s Getz Pharma (Pvt) Ltd, 29-30, Sector 27, Korangi Industrial Area, Karachi dated 09-06-2022

v. Relevant undertakings & commitments.

In the light of SOP approved by the Board in it 283rd meeting, after screening for administrative documents, the applications were forwarded to Pharmaceutical Evaluation Cell for scrutinization/evaluation. Detail of submitted documents & remarks of evaluator have been mentioned as under:

1428.	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablet, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 28-07-2022
	The proposed proprietary name / brand name	**Montiget Tablets 10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Montelukast as sodium ….10mg
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	14's
	Proposed unit price	Rs. 525.40/- for 14's
	The status in reference regulatory authorities	Singulair Tablets 10mg approved by US-FDA manufactured by Merck Sharp and Dohme Limited.
	For generic drugs (me-too status)	Montiget Tablets 10mg (Reg. No.:034838) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	**M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd.** located at No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies of Montiget Tablets 10mg against the reference product Singulair Tablets 10mg, in three dissolution mediums has been submitted with acceptable level of f2 results. **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Montiget Tablets 10mg against the reference product Singulair

		Tablets 10mg in routine release Medium with acceptable level of f2 results.
	Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance and drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions from existing site and stability studies data of two batches at initial, 3rd month and 6th month time interval (both accelerated and long term conditions) from new site.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)

Manufacturer of APIs	M/s. Morepen Laboratories Limited located at Village Masulkhana, Parwanoo, Distt. Solan [H.P.] India. M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd. located at No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.	0000112011, 0000113262		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 48 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36, 48 (Months)		
Batch No.	**157F13**	**158F13**	**159F13**
Batch Size	1,100,000 Tablets	1,100,000 Tablets	1,100,000 Tablets
Manufacturing Date	23-12-2015	20-02-2016	20.02.2016
Date of initiation	29-02-2016	25-03-2016	25-03-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. issued by China Food and Drug Administration valid till 03-14-2023. Firm has also submitted copy of GMP certificate of M/s Morepen Laboratories Limited issued by Licensing Authority cum Drug Controller, Himachal Pradesh valid till 31.12.2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
MLT5005	M/PD/2015-2016/236	50.00Kg	02-12-2015
MLT5013	M/PD/2015-2016/285	50.00Kg	01-01-2016

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted for 6 months data		
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)		
STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)				
Manufacturer of APIs		**M/s. Zhejiang Tianyu Pharmaceutical Co., Ltd.** located at No. 15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China.		
API Lot No.		0000200667		
Description of Pack (Container closure system)		Alu-Alu blister		
Stability Storage Condition		Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.		052ES01	053ES02	-
Batch Size		10,000 Tablets	10,000 Tablets	-
Manufacturing Date		28.01.2022	28.01.2022	-
Date of initiation		08.02.2022	08.02.2022	-
No. of Batches		02		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	--		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by China Food and Drug Administration valid till 03-14-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted		
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)		

Batch No.	**Invoice No.**	**Quantity Imported**	**Date of approval by DRAP**
11030-220101-06	21ATGZ106-107-108-1	65kg	20-01-2022

Remarks of the Evaluator:

The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.

- Stability Data of 2 stability batches at initial time point, 3rd Month & 6th Month interval have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against innovator from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP/DML of the API manufacturer submitted.

Section#	Observations	Firm's response
3.2.S.4.3	Performance of accuracy parameter shall be submitted for drug substance analytical method verification studies.	This is to bring to your kind attention that in ICH Guidelines "VALIDATION OF ANALYTICAL PROCEDURES: TEXT AND METHODOLOGY Q2 (R1)" it is mentioned in section 4.1.1 Drug Substance *"accuracy may be inferred once precision, linearity and specificity have been established".* This is bring to your kind attention that since we have performed method verification studies as per ICH Q2 (R1) including system suitability, specificity, linearity, repeatability and range. Therefore, requirement of accuracy is not applicable. However, as per requirement of your good office we have performed accuracy parameter for drug substance analytical method verification studies.
3.2.S.4.4	Submitted COA is form Morepen Laboratories whereas section 1.6.5 & section 3.2.S.2.1 declares drug substance manufacturer as M/s Zheijiang Tianyu Pharmaceutical Co., Ltd., China	This is to bring to your kind attention that submitted COAs from Morepen Laboratories Limited are COAs of relevant batch(es) of Drug Substance used during stability studies. Note: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., China is our current manufacturer of Montelukast Sodium for which we have submitted Drug Master File. However, stability batches on existing site have been manufactured by using Montelukast Sodium manufactured by M/s Morepen Laboratories Limited India. Please note that M/s Morepen Laboratories Limited India is our alternate approved manufacturer of Montelukast Sodium.

1429.	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 17-05-2022
	The proposed proprietary name / brand name	**Moxiget Tablets 400mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Moxifloxacin as hydrochloride …..400mg
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	Pharmacopoeia International
	Proposed Pack size	5's
	Proposed unit price	Rs.753.35/- (5's)
	The status in reference regulatory authorities	"Avelox Tablets 400mg" Approved by US-FDA by Bayer Pharms USA.
	For generic drugs (me-too status)	Moxiget Tablets 400mg (Reg. No.: 047117) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer	Zhejiang NHU Company Ltd., No.428 Xinchang Dadao West Road, Qixing Street, Xinchang County, Zhejiang Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of both drug substances.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi** Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies of Moxiget Tablets 400mg against the reference product Avelox Tablets 400mg, in three dissolution mediums has been submitted with acceptable level of f2 results.

<table>
<tr><td></td><td></td><td colspan="3">Getz Pharma (Pvt) Limited
Plot No. 01, Sector 25 Korangi Industrial Area, Karachi
Firm has also submitted the Comparative Dissolution Profile studies of Moxiget Tablets 400mg against the reference product Avelox Tablets 400mg, in Routine Release Medium with acceptable level of f2 results.</td></tr>
<tr><td></td><td>Analytical method validation / verification of product</td><td colspan="3">Firm has submitted verification studies of the drug substance & drug product.</td></tr>
<tr><td></td><td>Stability studies</td><td colspan="3">Firm has submitted stability studies data of three batches at both accelerated and long term conditions from existing site and stability studies data of two batches till 6th month time interval (both accelerated and long term conditions) from new site.</td></tr>
<tr><td></td><td>Claimed shelf life</td><td colspan="3">36 months</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">Zhejiang NHU Company Ltd.,
No.428 Xinchang Dadao West Road, Qixing Street, Xinchang County, Zhejiang Province, China</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">0000144224, 0000145221, 0000148313, 0000147612, 0000147613.</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 36 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Real Time: 0, 3, 6, 9, 12, 18, 24 & 36 (Months)
Accelerated: 0, 3 & 6 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>177F31</td><td>178F31</td><td>179F31</td></tr>
<tr><td colspan="2">Batch Size</td><td>525,000 Tablets</td><td>525,000 Tablets</td><td>525,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>08.06.2018</td><td>30.06.2018</td><td>02.07.2018</td></tr>
<tr><td colspan="2">Date of initiation</td><td>19.09.2018</td><td>28.09.2018</td><td>28.09.2018</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any).</td><td colspan="3">Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points:
• The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features:
✓ Have Audit trail
✓ Have backup system
✓ Have Data traceability
✓ Have Data achieving system
✓ Have data integrity
✓ Have Data security
✓ System Security Policy</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Firm has submitted copy of GMP certificate (Certificate # ZJ20180085) issued by China Food & Drug Administration valid till 02.08.2023.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Firm has submitted copy of commercial invoice attested by AD I&E DRAP, Karachi.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>AK180101</td><td>JC201801004-1</td><td>500 kg</td><td>12.01.2018</td></tr>
<tr><td>Y180102</td><td>JC201801002-1</td><td>100 kg</td><td>31.01.2018</td></tr>
<tr><td>18024MFH</td><td>ETS20171800077</td><td>250 kg</td><td>19.03.2018</td></tr>
<tr><td>18025MFH</td><td>ETS20171800077</td><td>250 kg</td><td>19.03.2018</td></tr>
<tr><td>Y180206</td><td>JC201803025-1</td><td>100 kg</td><td>04.04.2018</td></tr>
</table></td></tr>
</table>

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.		
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)		
STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)				
Manufacturer of APIs		Zhejiang NHU Company Ltd., No.428 Xinchang Dadao West Road, Qixing Street, Xinchang County, Zhejiang Province, China		
API Lot No.		0000192553		
Description of Pack (Container closure system)		Alu-Alu blister		
Stability Storage Condition		Real time: 30◦C ± 2◦C / 75% ± 5%RH Accelerated: 40◦C ± 2◦C / 75% ± 5%RH		
Time Period		Real time: 0, 3, 6 months Accelerated: 0, 3, 6 months		
Frequency		Accelerated: 0, 3, 6 months Real Time: Initial, 3, 6, 9, 12, 18, 24, 36 months		
Batch No.		048ES01	048ES02	-
Batch Size		10,000 Tablets	10,000 Tablets	-
Manufacturing Date		24.01.2022	24.01.2022	-
Date of initiation		07.02.2022	07.02.2022	-
No. of Batches		02		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	--		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (Certificate # ZJ20180085) issued by China Food and Drug Administration, valid till 02.08.2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice attested by AD I&E DRAP, Karachi.		

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
01210502MS	NL202104015-1	400 kg	23.06.2021

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

Details of documents submitted:

The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP for approval of post-registration variations approved in 283rd DRB meeting:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches (till 6 month time point) from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2020.

- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against innovator from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Executed Production document of stability batch.
- Process Validation Protocol from new site.
- Undertakings in accordance with SOP for approval of post-registration variations by DRAP.
- Analytical Method Verification studies of API & Finished product.
- Valid GMP Certificate of the API manufacturer.

Remarks of Evaluator:

- Dissolution test in International Pharmacopoeia recommends analysis of samples at 295nm wavelength of UV spectrophotometer, whereas firm has applied wavelength 294nm for dissolution test.
- Firm's response:
  Firm has referred to the following text of general chapter no. **1.6 Spectrophotometry in the visible and ultraviolet regions** of International Pharmacopoeia:
  "Good practice demands that use be made of the peak wavelength actually found in the individual instrument, rather than the specific wavelength given in the monograph, provided the two do not differ by more than ± 0.5 nm in the 240-280 nm range, by more than ± 1 nm in the 280-320nm range, and by more than ± 2 nm above 320 nm. If the difference is greater, recalibration of the instrument may be indicated."

1430.	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 19-05-2022
	The proposed proprietary name / brand name	**Cipesta Tablets 250mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ciprofloxacin USP….250mg (as hydrochloride)
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-infective for systemic use
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's
	Proposed unit price	Rs. 203.36/- for 10's
	The status in reference regulatory authorities	Cipro Tablets 250mg approved by US-FDA manufactured by Bayer Healthcare Pharmaceutical Inc., USA
	For generic drugs (me-too status)	Cipesta Tablets 250mg (Reg. No.:045372) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	**M/s Zhejiang Guobang Pharmaceutical Co., Ltd.** located at No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of

		manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Pharmaceutical Equivalence Studies of Cipesta Tablets 250mg against the reference product Ciproxin Tablets 250mg & Comparative Dissolution Profile studies of Cipesta Tablets 250mg against the reference product Cipro Tablets 250mg, in three dissolution mediums has been submitted with acceptable level of f2 results. **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Cipesta Tablets 250mg against the reference product Ciproxin Tablets 250mg in routine release medium wherein more than 85% of drug is released in 15 minutes.
	Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance and drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions and three ongoing batches at long term condition from Existing manufacturing site and stability studies of two batches at accelerated and long term condition from new manufacturing site.
	Clamed shelf life	36 months
STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)		
Manufacturer of APIs		M/s. Zhejiang Guobang Pharmaceutical Co., Ltd. located at No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.
API Lot No.		**Long Term and Accelerated Batches:** 0000176625, 0000188902, 0000188906, 0000189018 **Long Term Batches:** 0000109575, 0000121005, 0000149965
Description of Pack (Container closure system)		Alu-Alu blister
Stability Storage Condition		Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period		Accelerated: 6 months Long term: 36 months

<table>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>051F40</td><td>054F40</td><td>072F40</td></tr>
<tr><td colspan="2">Batch Size</td><td>400,000 Tablets</td><td>400,000 Tablets</td><td>400,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>16-06-2016</td><td>16-12-2016</td><td>14-09-2018</td></tr>
<tr><td colspan="2">Date of initiation</td><td>01-08-2016</td><td>24-03-2017</td><td>26-11-2018</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">06</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points:
The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features:
✓ Have Audit trail
✓ Have backup system
✓ Have Data traceability
✓ Have Data achieving system
✓ Have data integrity
✓ Have Data security
✓ System Security Policy</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Firm has submitted copy of GMP certificate issued by State Food and Drug Administration valid till 04-09-2023.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>104-200104-5</td><td>GBPH20200530</td><td>675kg</td><td>20-04-2020</td></tr><tr><td>105-210116-3</td><td>GBPH2021-1354</td><td>1,200kg</td><td>06-04-2021</td></tr><tr><td>105-210116-2</td><td>GPBH2021-1393</td><td>1,150kg</td><td>26-03-2021</td></tr><tr><td>DK15-1507043</td><td>JXHQ1509113</td><td>675kg</td><td>01-10-2015</td></tr><tr><td>DK15-1605072-A</td><td>JXHQ1606031</td><td>525kg</td><td>21-06-2016</td></tr><tr><td>DK15-1803012-A</td><td>JXHQ1804081</td><td>700kg</td><td>23-04-2018</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">M/s. Zhejiang Guobang Pharmaceutical Co., Ltd. located at No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">Ciprofloxacin : 0000197959</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Accelerated: 0, 3 (Months)
Real Time: 0, 3 (Months)</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>044ES01</td><td>044ES02</td><td>-</td></tr>
</table>

Batch Size		10,000 Tablets	10,000 Tablets	-
Manufacturing Date		21.01.2022	20.01.2022	-
Date of initiation		04.02.2022	04.02.2022	-
No. of Batches		02		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	--		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by State Food and Drug Administration valid till 04-09-2023.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.		

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
105-211025-1	GBPH2021-2766	500kg	01.12.2021

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

Remarks of the Evaluator:

The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches at initial and 3rd month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against innovator from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP of the API manufacturer submitted.

1431.	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.

	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 19-05-2022
	The proposed proprietary name / brand name	**Cipesta Tablets 500mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ciprofloxacin USP….500mg (as hydrochloride)
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Anti-infective for systemic use
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	10's
	Proposed unit price	Rs. 406.73/- for 10's
	The status in reference regulatory authorities	Cipro Tablets 500mg approved by US-FDA manufactured by Bayer Healthcare Pharmaceutical Inc., USA
	For generic drugs (me-too status)	Cipesta Tablets 500mg (Reg. No.:045373) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	**M/s. Zhejiang Guobang Pharmaceutical Co., Ltd.** located at No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Pharmaceutical Equivalence Studies of Cipesta Tablets 500mg against the reference product Ciproxin Tablets 500mg & Comparative Dissolution Profile studies of Cipesta Tablets 500mg against the reference product Cipro Tablets 500mg, in three dissolution mediums has been submitted with acceptable level of f2 results.

		Getz Pharma (Pvt) Limited **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Cipesta Tablets 500mg against the reference product Ciproxin Tablets 500mg in routine release medium wherein more than 85% of drug is released in 15 minutes.
	Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance and drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions and 3 batches at long term condition from Existing manufacturing site and stability studies of two batches at long term condition from new manufacturing site.
	Shelf life	36 months

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)				
Manufacturer of APIs		M/s. Zhejiang Guobang Pharmaceutical Co., Ltd. located at No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.		
API Lot No.		**Long Term and Accelerated Batches** 0000176625,0000176627, 0000185962 **Long Term Batches** 0000109575, 0000121005, 0000151445		
Description of Pack (Container closure system)		Alu-Alu blister		
Stability Storage Condition		Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 36 months Accelerated: months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.		**089F41**	**100F41**	**126F41**
Batch Size		325,000 Tablets	487,500 Tablets	487,500 Tablets
Manufacturing Date		04-05-2016	21-12-2016	08-08-2018
Date of initiation		23-06-2016	13-02-2017	19-10-2018
No. of Batches		06		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by State Food and Drug Administration valid till 04-09-2023.		

<table>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>104-200104-5</td><td>GBPH2020-0530</td><td>675kg</td><td>20-04-2020</td></tr><tr><td>104-200105-2</td><td>GBPH2020-0530</td><td>675kg</td><td>20-04-2020</td></tr><tr><td>105-200814-1</td><td>GBPH2020-2556</td><td>500kg</td><td>12-01-2021</td></tr><tr><td>DK15-1507043</td><td>JXHQ1509113</td><td>675kg</td><td>01-10-2015</td></tr><tr><td>DK15-1605072-A</td><td>JXHQ1606031</td><td>525kg</td><td>21-06-2016</td></tr><tr><td>DK15-1802282-B</td><td>JXHQ1805251</td><td>700kg</td><td>07-06-2018</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="4">STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">M/s. Zhejiang Guobang Pharmaceutical Co., Ltd. located at No. 6, Weiwu Road, Hangzhou Gulf Shangyu Economic and Technological Development Zone, Zhejiang, China.</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">0000197959</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Accelerated: 0, 3 (Months)
Real Time: 0, 3 (Months)</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>045ES01</td><td>045ES02</td><td>-</td></tr>
<tr><td colspan="2">Batch Size</td><td>10,000 Tablets</td><td>10,000 Tablets</td><td>-</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>21.01.2022</td><td>20.01.2022</td><td>-</td></tr>
<tr><td colspan="2">Date of initiation</td><td>04.02.2022</td><td>04.02.2022</td><td>-</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">02</td></tr>
<tr><td colspan="4">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">--</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Firm has submitted copy of GMP certificate issued by State Food and Drug Administration valid till 04-09-2023.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>105-211025-1</td><td>GBPH2021-2766</td><td>500kg</td><td>01.12.2021</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
</table>

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

Remarks of the Evaluator:

The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches at initial & 3rd month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against innovator from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP of the API manufacturer submitted.

1432.	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 19.05.2022
	The proposed proprietary name / brand name	**Nebil Tablets 2.5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…2.5mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Beta blocking agents ATC code: C07AB12
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10's & 14's
	Proposed unit price	Rs.127.75/- (10's) and Rs. 170.34/- (14's)
	The status in reference regulatory authorities	BYSTOLIC 2.5mg Tablet by M/s Allergan, USA. USFDA Approved.
	For generic drugs (me-too status)	Nebil Tablets 2.5mg (Reg. No.: 061344) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi

	Name and address of API manufacturer.	Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002, Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (17NV001, 17NV002, 17NV003)
	Module-III Drug Product:	Firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29-30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Nebil Tablets 2.5mg against the reference product Bystolic 2.5mg Tablet by (M/s Allergan, USA.), in three dissolution mediums has been submitted with acceptable level of f2 results. Pharmaceutical Equivalence Studies of Nebil Tablets 2.5mg against the reference product Bystolic 2.5mg Tablet by (M/s Allergan, USA.) by performing quality tests (Appearance, Average weight, Assay and Dissolution) has been submitted. **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Nebil Tablets 2.5mg (new site) against the reference product Nebil Tablets 2.5mg (existing site) in Routine Release Medium wherein more than 85% of drug is released in 15 minutes.
	Analytical method validation/ verification of product	Firm has submitted verification/validation studies of the drug substance and drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions and three ongoing batches at long term condition from existing manufacturing site and stability studies of two batches at accelerated and long term condition from new manufacturing site.
	Claimed shelf life	36 months
STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)		
Manufacturer of APIs		Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002, Gujarat, INDIA
API Lot No.		0000103982, 0000149726 & 0000155000

<table>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3"><table><tr><th>Long Term and Accelerated Batches</th><th>Long Term Batches</th></tr><tr><td>028T60
Accelerated: 6 months
Real time: 36 months</td><td>083T60
Real time: 24 months</td></tr><tr><td>029T60
Accelerated: 6 months
Real time: 36 months</td><td>177T60
Real time: 24 months</td></tr><tr><td>030T60
Accelerated: 6 months
Real time: 36 months</td><td>194T60
Real time: 24 months</td></tr></table></td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>028T60</td><td>029T60</td><td>030T60</td></tr>
<tr><td colspan="2">Batch Size</td><td>200,000 Tablets</td><td>200,000 Tablets</td><td>200,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>19.03.2013</td><td>10.04.2013</td><td>29.04.2013</td></tr>
<tr><td colspan="2">Date of initiation</td><td>04.05.2013</td><td>21.05.2013</td><td>03.06.2013</td></tr>
<tr><td colspan="2">Batch No.</td><td>083T60</td><td>177T60</td><td>194T60</td></tr>
<tr><td colspan="2">Batch Size</td><td>200,000 Tablets</td><td>400,000 Tablets</td><td>400,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>07.10.2015</td><td>24.09.2018</td><td>14.03.2019</td></tr>
<tr><td colspan="2">Date of initiation</td><td>18.11.2015</td><td>05.11.2018</td><td>17.05.2019</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">06</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points:
The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features:
✓ Have Audit trail
✓ Have backup system
✓ Have Data traceability
✓ Have Data achieving system
✓ Have data integrity
✓ Have Data security
✓ System Security Policy</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Copy of GMP Certificate no. 21102987 issued by Food & Drugs Control Administration, Gujrat valid till 20-10-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>15NV005</td><td>CPL/BD/108/15-16</td><td>10Kg</td><td>24.06.2015</td></tr><tr><td>18NV009</td><td>3201840035</td><td>20Kg</td><td>03.05.2018</td></tr><tr><td>18NV020</td><td>3201540290</td><td>20Kg</td><td>02.10.2018</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
</table>

<table>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">Cadila Pharmaceuticals Limited.
294, G.I.D.C. Industrial Estate
Ankleshwar - 393 002, Gujarat, INDIA</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">0000193904</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>046ES01</td><td>046ES02</td><td>-</td></tr>
<tr><td colspan="2">Batch Size</td><td>10,000 Tablets</td><td>10,000 Tablets</td><td>-</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>21-01-2022</td><td>21-01-2022</td><td>-</td></tr>
<tr><td colspan="2">Date of initiation</td><td>03-02-2022</td><td>03-02-2022</td><td>-</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">02</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">--</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Copy of GMP Certificate no. 21102987 issued by Food & Drugs Control Administration, Gujrat valid till 20-10-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>21NV016</td><td>3202140419</td><td>20 Kg</td><td>02.09.2021</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="5">Miscellaneous documents submitted:
The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:
• Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29-30, Sector 27, Korangi Industrial Area.
• Stability Data of 2 stability batches till 6 month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
• Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against comparator from new manufacturing facility.
• Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
• Firm has submitted Executed Production document of stability batch.</td></tr>
</table>

- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP of the API manufacturer submitted.

Remarks of Evaluator:

Firm has submitted following set of data from old site:

Batch No.	Date	Stability Duration	Batch No.	Date	Stability Duration
Without Chromatograms, Raw Data and Calculation Sheets			With Chromatograms, Raw Data and Calculation Sheets		
028T60	Mfg.: 19.03.2013 Exp.: 19.03.2015	Accelerated: 6 months Real Time: 36 Months	083T60	Mfg.: 07.10.2015 Exp.: 07.10.2017	Real Time: 24 Months
029T60	Mfg.: 10.04.2013 Exp.: 10.04.2015	Accelerated: 6 months Real Time: 36 Months	177T60	Mfg.: 24.09.2018 Exp.: 24.09.2020	Real Time: 24 Months
030T60	Mfg.: 29.04.2013 Exp.: 29.04.2015	Accelerated: 6 months Real Time: 36 Months	194T60	Mfg.: 14.03.2019 Exp.: 14.03.2021	Real Time: 24 Months

On basis of above cited data firm has claimed 36 months shelf life.

1433.		
	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 17.05.2022
	The proposed proprietary name / brand name	**Nebil Tablets 5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…5mg
	Pharmaceutical form of applied drug	Tablets
	Pharmacotherapeutic Group of (API)	Beta blocking agents ATC code: C07AB12
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	10's & 14's
	Proposed unit price	Rs.212.93/- (10's) and Rs. 283.90/- (14's)
	The status in reference regulatory authorities	BYSTOLIC 5mg Tablet by M/s Allergan, USA. USFDA Approved.

	For generic drugs (me-too status)	Nebil Tablets 5mg (Reg. No.: 061345) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002, Gujarat, INDIA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (17NV001, 17NV002, 17NV003)
	Module-III Drug Product:	Firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29-30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Nebil Tablets 5mg against the reference product Nebilet Tablets 5mg (M/s Berlin-Chemie AG Germany), in three dissolution mediums has been submitted with acceptable level of f2 results. Pharmaceutical Equivalence Studies of Nebil Tablets 5mg against the reference product Nebilet Tablets 5mg (M/s Berlin-Chemie AG Germany), by performing quality tests (Appearance, Average weight, Assay and Dissolution) has been submitted. **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Nebil Tablets 5mg (new site) against the reference product Nebil Tablets 5mg (existing site) in Routine Release Medium wherein more than 85% of drug is released in 15 minutes.
	Analytical method validation/ verification of product	Firm has submitted verification/validation studies of the drug substance and drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions and three ongoing batches at long term condition from existing manufacturing site and stability studies of two batches at accelerated and long term condition from new manufacturing site.
STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)		
Manufacturer of APIs		Cadila Pharmaceuticals Limited. 294, G.I.D.C. Industrial Estate Ankleshwar - 393 002, Gujarat, INDIA

<table>
<tr><td colspan="2">API Lot No.</td><td colspan="3">0000136610, 0000141695 & 0000155000</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3"><table><tr><th>Long Term and Accelerated Batches</th><th>Long Term Batches</th></tr><tr><td>040T61
Accelerated: 6 months
Real time: 36 months</td><td>231T61
Real time: 24 months</td></tr><tr><td>041T61
Accelerated: 6 months
Real time: 36 months</td><td>242T61
Real time: 24 months</td></tr><tr><td>042T61
Accelerated: 6 months
Real time: 36 months</td><td>302T61
Real time: 24 months</td></tr></table></td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>040T61</td><td>041T61</td><td>042T61</td></tr>
<tr><td colspan="2">Batch Size</td><td>150,000 Tablets</td><td>150,000 Tablets</td><td>150,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>01.04.2013</td><td>01.04.2013</td><td>01.04.2013</td></tr>
<tr><td colspan="2">Date of initiation</td><td>04.05.2013</td><td>04.05.2013</td><td>21.05.2013</td></tr>
<tr><td colspan="2">Batch No.</td><td>231T61</td><td>242T61</td><td>302T61</td></tr>
<tr><td colspan="2">Batch Size</td><td>300,000 Tablets</td><td>300,000 Tablets</td><td>300,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>26.10.2017</td><td>30.01.2018</td><td>11.02.2019</td></tr>
<tr><td colspan="2">Date of initiation</td><td>04.12.2017</td><td>26.04.2018</td><td>17.05.2019</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">06</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points:
The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features:
✓ Have Audit trail
✓ Have backup system
✓ Have Data traceability
✓ Have Data achieving system
✓ Have data integrity
✓ Have Data security
✓ System Security Policy</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Copy of GMP Certificate no. 21102987 issued by Food & Drugs Control Administration, Gujrat valid till 20-10-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>17NV011</td><td>CPL/BD/114/17-18</td><td>10Kg</td><td>09.06.2017</td></tr><tr><td>17NV024</td><td>CPL/BD/378/17-18</td><td>10Kg</td><td>07.11.2017</td></tr><tr><td>18NV020</td><td>3201540290</td><td>20Kg</td><td>02.10.2018</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
</table>

<table>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">Cadila Pharmaceuticals Limited.
294, G.I.D.C. Industrial Estate
Ankleshwar - 393 002, Gujarat, INDIA</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">0000193904</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>047ES01</td><td>047ES02</td><td>-</td></tr>
<tr><td colspan="2">Batch Size</td><td>10,000 Tablets</td><td>10,000 Tablets</td><td>-</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>21-01-2022</td><td>21-01-2022</td><td>-</td></tr>
<tr><td colspan="2">Date of initiation</td><td>03-02-2022</td><td>03-02-2022</td><td>-</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">02</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">--</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Copy of GMP Certificate no. 21102987 issued by Food & Drugs Control Administration, Gujrat valid till 20-10-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>21NV016</td><td>3202140419</td><td>20 Kg</td><td>02.09.2021</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
</table>

Miscellaneous documents:

The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29-30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches till 6 month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
- Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against comparator from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Firm has submitted Executed Production document of stability batch.
- Firm has submitted Process Validation Protocol.
- Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
- Analytical Method Verification / validation studies of API & Finished product.
- Valid GMP of the API manufacturer submitted.

Remarks of Evaluator:

Firm has submitted following set of data from old site:

Batch No.	Date	Stability Duration	Batch No.	Date	Stability Duration
Without Chromatograms, Raw Data and Calculation Sheets			With Chromatograms, Raw Data and Calculation Sheets		
040T61	Mfg.: 01.04.2013 Exp.: 01.04.2015	Accelerated: 6 months Real Time: 36 Months	231T61	Mfg.: 26.10.2017 Exp.: 26.10.2019	Real Time: 24 Months
041T61	Mfg.: 01.04.2013 Exp.: 01.04.2015	Accelerated: 6 months Real Time: 36 Months	242T61	Mfg.: 30.01.2018 Exp.: 30.01.2020	Real Time: 24 Months
040T61	Mfg.: 01.04.2013 Exp.: 01.04.2015	Accelerated: 6 months Real Time: 36 Months	302T61	Mfg.: 11.02.2019 Exp.: 11.02.2021	Real Time: 24 Months

On basis of above cited data firm has claimed 36 months shelf life.

1434.		
	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 28.09.2022
	The proposed proprietary name / brand name	**Diampa-M Tablets 12.5mg + 1000mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….12.5mg Metformin HCl USP….1000mg
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's
	Proposed unit price	Rs. 666.18/- (14's)
	The status in reference regulatory authorities	Synjardy 12.5mg + 1000mg Tablets by M/s Boehringer Ingelheim, USA. USFDA Approved.
	For generic drugs (me-too status)	Diampa-M Tablets 12.5mg + 1000mg (Reg. No.: 093084) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**Empagliflozin:** Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin HCl:** Official monograph of Metformin HCl is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04) **Metformin HCl:** Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-72611405016, A-72611405017, A-72611405018)

	Module-III Drug Product:	Firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29-30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Diampa-M Tablets 12.5mg + 1000mg against the reference product Jardiance Duo Tablets 12.5mg/1mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), in three dissolution mediums has been submitted wherein more than 85% of drug is released in 15 minutes. Pharmaceutical Equivalence Studies of Diampa-M Tablets 12.5mg + 1000mg against the reference product Jardiance Duo Tablets 12.5mg/1mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), by performing quality tests (Appearance, Average weight, Assay and Dissolution). **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)** Firm has also submitted the Comparative Dissolution Profile studies of Diampa-M Tablets 12.5mg + 1000mg (new site) against the reference product Diampa-M tablets 12.5mg + 1000mg (existing site) in Routine Release Medium wherein more than 85% of drug is released in 15 minutes.
	Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance and drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions form existing manufacturing site and stability studies of two batches from new manufacturing site.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)			
Manufacturer of APIs	**Empagliflozin:** Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, 237 provincial highway, Jiangsu Huai'an Economic Development, Jiangsu, China. **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.		
API Lot No.	**Empagliflozin:** 0000171080, 0000171936 **Metformin HCl:** 0000171368, 0000173981		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	**066FC2**	**067FC2**	**068FC2**
Batch Size	100,000 Tablets	100,000 Tablets	100,000 Tablets
Manufacturing Date	06-03-2020	11-03-2020	29-04-2020
Date of initiation	01-07-2020	01-07-2020	16-07-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and

<table>
<tr><td></td><td>the firm (if any)</td><td>approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points:
The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features:
✓ Have Audit trail
✓ Have backup system
✓ Have Data traceability
✓ Have Data achieving system
✓ Have data integrity
✓ Have Data security
✓ System Security Policy</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Empagliflozin:
Copy of Drug Manufacturing License no. Su 20160324 issued by Jiangsu Drug Administration (Huai'an Inspection Branch) valid till 06-12-2025.

Metformin HCl:
Copy of GMP Certificate No. SD20190888 issued by CFDA, China valid till 12-03-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>20191126</td><td>JXCAVIR-20191101AP</td><td>30kg</td><td>16-12-2019</td></tr><tr><td>20191130</td><td>JXCAVIR-20191003AP</td><td>20kg</td><td>07-01-2020</td></tr></table>
Metformin HCl:<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>A-32611909014</td><td>JC201910011-1</td><td>2000Kg</td><td>11-12-2019</td></tr><tr><td>A-32611910003</td><td>JC201910012-2</td><td>2000Kg</td><td>07-01-2020</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td>Empagliflozin:
Fuxin Long Rui Pharmaceutical Co., Ltd.
Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China

Metformin HCl:
Shouguang Fukang Pharmaceutical Co., Ltd.
North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang City, Shandong Province, China.</td></tr>
<tr><td colspan="2">API Lot No.</td><td>Empagliflozin: 0000193486
Metformin HCl: 0000193122</td></tr>
</table>

<table>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>053ES01</td><td>053ES02</td><td>-</td></tr>
<tr><td colspan="2">Batch Size</td><td>10,000 Tablets</td><td>10,000 Tablets</td><td>-</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>31.01.2022</td><td>31.01.2022</td><td>-</td></tr>
<tr><td colspan="2">Date of initiation</td><td>08.02.2022</td><td>08.02.2022</td><td>-</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">02</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">--</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Empagliflozin:
Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 20-12-2022.

Metformin HCl:
Copy of GMP Certificate No. SD20190888 issued by CFDA, China valid till 12-03-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>H-E-2021 0605-D01-E06-01</td><td>HN20210625-E</td><td>60 Kg</td><td>23.08.2021</td></tr>
</table>
Metformin HCl:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>A-326121 05020-0150</td><td>JC202105010-1</td><td>2000 kg</td><td>05.07.2021</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).</td></tr>
<tr><td colspan="5">Miscellaneous documents:
The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP guidelines stated in 283rd DRB meeting minutes:
Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
Stability Data of 2 stability batches till 6th month time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.</td></tr>
</table>

• Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against reference product from new manufacturing facility. • Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility. • Firm has submitted Executed Production document of stability batch. • Firm has submitted Process Validation Protocol. • Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. • Analytical Method Verification / validation studies of API & Finished product. • Valid GMP/DML of the API manufacturer submitted.		
Remarks of Evaluator: The source of Empagliflozin from old site was M/s Jiangsu Yongan, whereas at new site source of Empagliflozin is M/s Fuxin Long Rui, China.		
1435.	Name, address of Applicant / Marketing Authorization Holder.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted Drug Manufacturing License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablets, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Details of fee submitted	PKR 30,000/-: 28.07.2022
	The proposed proprietary name / brand name	**Diampa-M Tablets 5mg + 1000mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin….5mg Metformin HCl USP….1000mg
	Pharmaceutical form of applied drug	Film-coated Tablets
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs ATC Code: A10BD20
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's & 28's
	Proposed unit price	Rs. 647.37/- (14's) & Rs. 1268.73/- (28's)
	The status in reference regulatory authorities	Synjardy 5mg + 1g Tablets by M/s Boehringer Ingelheim, USA. USFDA Approved.
	For generic drugs (me-too status)	Diampa-M Tablets 5mg + 1000mg (Reg. No.: 103094) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang, Shandong, China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	**Empagliflozin:** Official monograph of Empagliflozin is not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin HCl:** Official monograph of Metformin HCl is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-E-20200409-D01-E06-02, L-E-20200409-D01-E06-03, L-E-20200409-D01-E06-04) **Metformin HCl:** Real time: 30°C ± 2°C / 75% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-72611405016, A-72611405017, A-72611405018)
	Module-III Drug Product:	Firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited** **Plot no. 29-30, sector 27 Korangi Industrial Area, Karachi (Existing Facility)** Comparative Dissolution Profile studies of Diampa-M Tablets 5mg + 1000mg against the reference product Jardiance Duo Tablets 5mg/1mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany) in three dissolution mediums has been submitted wherein more than 85% of drug is released in 15 minutes. Pharmaceutical Equivalence Studies of Diampa-M Tablets 5mg + 1000mg against the reference product Jardiance Duo Tablets 5mg/1mg (M/s Boehringer Ingelheim Pharma GmbH & Co., Germany), by performing quality tests (Appearance, Average weight, Assay and Dissolution). **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi (New Facility)**

		Firm has also submitted the Comparative Dissolution Profile studies of Diampa-M Tablets 5mg + 1000mg (new site) against the reference product Diampa-M Tablets 5mg + 1000mg (existing site) in Routine Release Medium wherein more than 85% of drug is released in 15 minutes.		
	Analytical method validation / verification of product	Firm has submitted verification / validation studies of the drug substance and drug product.		
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.		
STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)				
Manufacturer of APIs		**Empagliflozin:** Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, 237 provincial highway, Jiangsu Huai'an Economic Development, Jiangsu, China. Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **Metformin HCl:** Shouguang Fukang Pharmaceutical Co., Ltd. North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang, Shandong, China.		
API Lot No.		**Empagliflozin:** 0000173622 (Jiangsu Yongan) 0000178438 (Fuxin Long Rui) **Metformin HCl:** 0000175784, 0000175788		
Description of Pack (Container closure system)		Alu-Alu blister		
Stability Storage Condition		Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 24 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)		
Batch No.		**001FD8**	**002FD8**	**003FD8**
Batch Size		110,000 Tablets	110,000 Tablets	110,000 Tablets
Manufacturing Date		08.06.2020	30.06.2020	30.06.2020
Date of initiation		21.08.2020	04.09.2020	04.09.2020
No. of Batches		03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Onsite inspection report of Getz Pharma product Emclide (Empagliflozin & Linagliptin) Tablets 10mg + 5mg was discussed and approved in 316th RB Meeting held on March 15-18, 2022. The inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of HPLC with Empower 3 and DB software having following features: ✓ Have Audit trail ✓ Have backup system ✓ Have Data traceability ✓ Have Data achieving system ✓ Have data integrity ✓ Have Data security ✓ System Security Policy		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Copy of Drug Manufacturing License no. Su 20160324 issued by Jiangsu Drug Administration valid till 06-12-2025. Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 20-12-2022.		

<table>
<tr><td></td><td></td><td>Metformin HCl:
Copy of GMP Certificate No. SD20190888 issued by CFDA, China valid till 12-03-2024.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Karachi, has been submitted.

Empagliflozin:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>20191203 (Jiangsu Yongan)</td><td>JXCAVIR-200101</td><td>30Kg</td><td>18.02.2020</td></tr>
<tr><td>L-E-20200409-D-01-E06-01 (Fuxin Long Rui)</td><td>SY20061202-E</td><td>50Kg</td><td>18.06.2020</td></tr>
</table>
Metformin HCl:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>A-81412001021</td><td rowspan="2">JC201911021-1</td><td>2,000Kg</td><td rowspan="2">06.04.2020</td></tr>
<tr><td>A-81412001017</td><td>2,000Kg</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance certificate of HPLC software.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td>Empagliflozin:
Fuxin Long Rui Pharmaceutical Co., Ltd.
Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China

Metformin HCl:
Shouguang Fukang Pharmaceutical Co., Ltd.
North-East of Dongwaihuan Road, Dongcheng Industrial Area, Shouguang, Shandong, China.</td></tr>
<tr><td colspan="2">API Lot No.</td><td>Empagliflozin: 0000193486
Metformin HCl: 0000193122</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td>Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td>Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td>Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Frequency</td><td>Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18 & 24 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>054ES01</td><td>054ES02</td><td>-</td></tr>
<tr><td colspan="2">Batch Size</td><td>10,000 Tablets</td><td>10,000 Tablets</td><td>-</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>31.01.2022</td><td>31.01.2022</td><td>-</td></tr>
<tr><td colspan="2">Date of initiation</td><td>08.02.2022</td><td>08.02.2022</td><td>-</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">02</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
</table>

<table>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td>--</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Empagliflozin:
Copy of Drug Manufacturing License no. LIAO 20150233 issued by Liaoning Medical Products Administration valid till 20-12-2022.

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Empagliflozin:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>H-E-2021 0605-D01-E06-01</td><td>HN20210625-E</td><td>60 Kg</td><td>23.08.2021</td></tr>
</table>
Metformin HCl:
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>A-326121 05020-0150</td><td>JC202105010-1</td><td>2,000 Kg</td><td>05.07.2021</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
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Stability Data of 2 stability batches till 06 months time point have also been submitted by manufacturer from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2021.
Comparative Dissolution Profile and Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against comparator from new manufacturing facility.
Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
Firm has submitted Executed Production document of stability batch.
Firm has submitted Process Validation Protocol.
Firm has submitted undertakings that process validation, accelerated and real time stability studies on 03 commercial batches at new manufacturing facility will be conducted & in case of any quality complaint / OOS result as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
Analytical Method Verification / validation studies of API & Finished product.
Valid GMP/DML of the API manufacturer submitted.</td></tr>
<tr><td colspan="3">Remarks of Evaluator:
The source of Empagliflozin from old site was M/s Jiangsu Yongan, whereas at new site source of Empagliflozin is M/s Fuxin Long Rui, China.</td></tr>
</table>

Decision **Registration Board decided as under:**

i. Cancelled registration of following products from the name of M/s Getz Pharma (Pvt) Ltd, 29-30, Sector 27, Korangi Industrial Area, Karachi (DML No. 000284).

S. No.	Reg. No.	Product Name & Composition
1.	045372	Cipesta Tablets 250mg Each film coated tablet contains: Ciprofloxacin (as Hydrochloride)……..250mg (USP Specifications)
2.	045373	Cipesta Tablets 500mg Each film coated tablet contains: Ciprofloxacin (as Hydrochloride)……..500mg (USP Specifications)
3.	061344	Nebil Tablets 2.5mg Each tablet contains: Nebivolol as HCl……..2.5mg (Manufacturer's Specifications)
4.	061345	Nebil Tablets 5mg Each tablet contains: Nebivolol as HCl……..5mg (Manufacturer's Specifications)
5.	034838	Montiget 10mg Tablets Each film coated tablet contains: Montelukast (as Sodium Salt)……10mg
6.	047117	Moxiget 400mg Tablets Each tablet contains: Moxifloxacin (as Hydrochloride)…400mg (Manufacturer's Specification)
7.	103094	Diampa-M Tablet 5mg + 1000mg Each film coated tablet contains:- Empagliflozin ……..….. 5mg Metformin Hydrochloride…….. 1000mg (As per *Innovator's Specifications)
8.	093084	Diampa-M Tablet 12.5mg + 1000mg Each film coated tablet contains:- Empagliflozin …….. 12.5mg Metformin Hydrochloride…… ….. 1000mg (As per *Innovator's Specifications)

ii. Approved registration of following products in the name of M/s Getz Pharma (Pvt) Ltd, Plot No.01, Sector 25, Korangi Industrial Area, Karachi (DML No. 000933) with same registration numbers in the light of legal opinion furnished by Legal Affairs Division, DRAP vide letter F.No. 11-1/2018/DD(LA)-Vol-I dated 05-10-2021.

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

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name, Composition, FPP Specifications & Shelf Life
1.	Cipesta Tablets 250mg Each film coated tablet contains: Ciprofloxacin (as Hydrochloride)……..…..250mg (USP Specifications) (Shelf life: 24 Months)

2.	**Cipesta Tablets 500mg** **Each film coated tablet contains:** **Ciprofloxacin (as Hydrochloride)……..500mg** **(USP Specifications)** **(Shelf life: 24 Months)**
3.	**Nebil Tablets 2.5mg** **Each tablet contains:** **Nebivolol Hydrochloride Eq. to Nebivolol……..2.5mg** **(As per Innovator's Specifications)** **(Shelf life: 24 Months)**
4.	**Nebil Tablets 5mg** **Each tablet contains:** **Nebivolol Hydrochloride Eq. to Nebivolol……..5mg** **(As per Innovator's Specifications)** **(Shelf life: 24 Months)**
5.	**Montiget 10mg Tablets** **Each film coated tablet contains:** **Montelukast as Sodium…….……10mg** **(USP Specifications)** **(Shelf life: 24 Months)**
6.	**Moxiget 400mg Tablets** **Each film coated tablet contains:** **Moxifloxacin as Hydrochloride……..…400mg** **(IP Specifications)** **(Shelf life: 24 Months)**
7.	**Diampa-M Tablet 5mg + 1000mg** **Each film coated tablet contains:-** **Empagliflozin ……..….. 5mg** **Metformin Hydrochloride…….. 1000mg** **(As per *Innovator's Specifications)** **(Shelf life: 24 Months)**
8.	**Diampa-M Tablet 12.5mg + 1000mg** **Each film coated tablet contains:-** **Empagliflozin ……..….. 12.5mg** **Metformin Hydrochloride…… ……..….. 1000mg** **(As per *Innovator's Specifications)** **(Shelf life: 24 Months)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No I- Previous Agenda of 316th Meeting of CLB regarding Colistimethate Sodium:

Review of Colistimethate for Injection:

The product label of innovator product Coly-Mycin® M Parenteral (Colistimethate for Injection, USP) approved in USFDA is as below:

Each vial contains:

Colistimethate Sodium (150 mg colistin base activity).

In the EU, the dose of Colistimethate sodium (CMS) is prescribed and administered as International Units (IU). The product label states the number of IU per vial.

In the US, the dose is expressed as milligrams of colistin base activity (mg CBA). The relationship between IU and CBA is as follows wherein the values are taken approximate only.

CMS conversion table

Potency ≈		**mass of CMS (mg)***
IU	**≈ mg CBA**	
12,500	0.4	1
150,000	5	12
1,000,000	34	85
4,500,000	150	360
9,000,000	300	720

*Nominal potency of the drug substance = 12,500 IU/mg

USP monograph states the following label claim for Colistimethate for Injection.

"Colistimethate for Injection contains an amount of Colistimethate sodium equivalent to not less than 90.0 percent and not more than120.0 percent of the labeled amount of Colistin".

According to **BP monograph**, the label of sealed container states the total number of IU (units) contained in it.

Previous Decision of 316th meeting:

Registration Board decided to defer the case for further deliberation and advised PE&R Division to present the case in forthcoming meeting along with details of already registered products along with its label claim and specifications.

Details of registered imported products

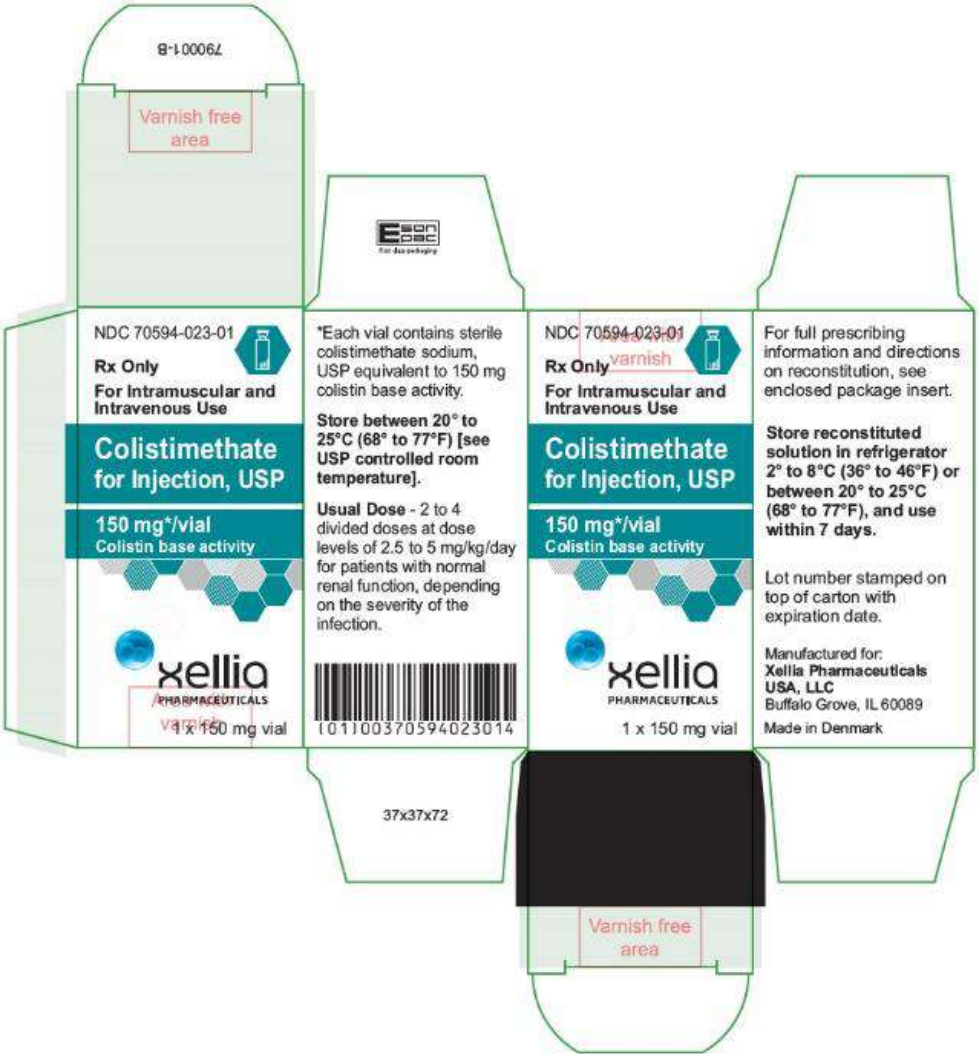
REG. NO.	DRUGS NAME	COMPOSITION OF THE DRUG	MANUFACTURER	COUNTRY NAME	IMPORTER NAME
093937	COLISTIMETHATE SODIUM POWDER FOR SOLUTION FOR IV INJECTION/ INFUSION	EACH VIAL 10ML CONTAINS:- COLISTIMETHATE SODIUM…….. 1MIU **(USP SPECIFICATION)**	M/S. XELLIA PHARMACEUTICALS APS DALSLANDSGADE11, 2300 COPENHAGEN S DENMARK.	DENMARK	M/S. MUKHTAR ENTERPRISES, LAHORE.
094751	COLICRAFT 2MIU LYPHOLIZED POWDER FOR SOLUTION FOR INJECTION	EACH VIAL CONTAINS:- COLISTIMETHATE SODIUM…2,000,000 U.I **(USP SPECIFICATIONS)**	MANUFACTURER: - M/S. GENFARMA LABORATORIO, S.L. AVDA. DE LA CONSTITUCION, 198, POL. INDUSTRIAL MONTE BOYAL, 45950 CASARRUBIOS DEL MONTE (TOLEDO) ESPANA, SPAIN.	SPAIN	M/S. REVIVE HEALTHCARE, Lahore.
094757	COLISTIMETHATE SODIUM POWDER FOR SOLUTION FOR IV INJECTION / INFUSION	EACH VIAL CONTAINS: COLISTIMETHATE SODIUM…….. 2MIU **(USP SPECIFICATION)**	MANUFACTURER & PRODUCT LICENSE HOLDER:- M/S XELLIA PHARMACEUTICALS APS DALSLANDGADE 11, 2300 COPENHAGEN S DENMARK.	DENMARK	M/S. MUKHTAR ENTERPRISES, LAHORE.
103783	CBA 150 INJECTION (POWDER FOR SOLUTION FOR INJECTION)	EACH VIAL CONTAINS: COLISTIMETHATE SODIUM EQ. TO COLISTIN ……. 150MG **(USP SPECIFICATIONS)**	MARKETING AUTHORIZATION HOLDER & MANUFACTURER:- M/S ATLANTIC LABORATORIES CORPORATION, LTD. 111 MOO 7, BANG PHLI NOI, BANG BO, SAMUT PRAKAN 10560 THAILAND.	THAILAND	M/S BIOCARE PHARMACEUTICA, (SHAH JAMAL, LAHORE)

110490	KOLISOD 150MG LYOPHILIZED POWER FOR INJECTION AND INHALATION VIAL	EACH VIAL CONTAINS:- COLISTIMETHATE SODIUM.....384.615MG (=150MG COLISTIN BASE) (USP SPECIFICATION) DILUENT WATER FOR INJECTION……..2ML **(USP SPECIFICATION)**	MANUFACTURER: M/S VEM ILAC SAN. VE TIC. A.S. CERKEZKOY ORGANIZE SANAYI BOLGESI KARAAGAC MAHALLESI FATIH BULVARI NO: 38 KAPAKLI, TEKIRDAG, TURKEY.	TURKEY	M/S. BRISTOL MAYER BIOTECH PAKISTAN, 73-B GULDASHAT TOWN, ZARRAR SHAHEED ROAD,LAHORE.

Details of registered Local manufacturing products

Registration No	Approved Brand Name	Ref Unit	Composition	Specification	Company Name
76160	Colistat powder for Injection	Each vial contains	Colistimethate Sodium_ 1 million I.U-	BP	Medisure Laboratories Pakistan (Pvt)Ltd.
82407	Colicraft Injection	Each vial contains	Colistimethate sodium (lyophilized powder)_ 1 MIU-	USP	Bio-Labs(Pvt) Ltd
89922	Colistim Injection 80mg	Each vial contains	Colistimethate Sodium powder for reconstitution_ 80 mg-	USP	Pharmasol (Pvt) Ltd, Lahore
92316	Colitec 1MIU Injection	Each vial contains	Colistimethate Sodium_ 1 MIU-	USP	Rotex Pharma (Pvt) Ltd.Islamabad
92529	Coliate IV Injection	Each vial contains	Colistimethate Sodium_ 1 MIU-	USP	English Pharmaceutical Indsutries,Lahore.
97779	Colimate 100,0000 IU Injection	Each lyophilized vial contains	Colistimethate Sodium_ 1000000 IU-	USP	MTI Medical (Pvt) Ltd , Lahore
103512	Closmat Injection 1 Million IU Lyophilized Powder for solution for Injection/ Infusion	Each vial contains	Colistimethate Sodium_ 1 Million IU-	BP	CCL Pharmaceuticals (Pvt.) Ltd.Lahore
104498	Colistitek Injection 1M IU	Each vial contains	Colistimethate Sodium Powder 1million International Units _ 80 mg-	USP	Wellborne pharmachem&biologicals
105370	Colybid Injection 1M IU	Each vial contains	Colistimethate Sodium_ 1 Million IU-	USP	SAFE PHARMACEUTICAL (PVT) LTD
106475	Stacolmi 1MIU Injection	Each vial contains	Colistimethate Sodium_ 1 MIU-	USP	STALLION PHARMACEUTICALS PVT LTD
106889	Cricolist Dry powder for Injection	Each vial contains	Colistimethate Sodium_ 1 MIU-	USP	FYNK Pharmaceuticals,Lahore
107383	Mellistin Injection 1Million IU	Each vial contains	Colistimethate Sodium_ 1 Million IU-	USP	Macter International Ltd.Karachi
107472	Nogotex Injection 1 Million IU	Each vial contains	Colistimethate sodium (lyophilized powder)_ 1 MIU-	USP	Nabi Qasim Industries Pvt Ltd,Karachi
107596	Cmyate Powder For Solution For Injection 1MIU (IV)	Each vial contains	Colistimethate Sodium 1million International Units eq. to_ 80 mg-	USP	Aulton Pharmaceuticals , Hattar
107612	Colmixin Powder For Solution For Injection 1MIU (IV)	Each vial contains	Colistimethate Sodium 1million International Units eq. to_ 80 mg-	USP	Genix Pharma (Pvt) Ltd., Karachi
107733	Colimethate Powder for Solution for Injection/Infusion **2MIU** IV	Each vial contains	Colistimethate Sodium 2 Million International Units (IU) Eq. to_ 160 mg-	USP	TABROS PHARMA (PVT). LTD.
108054	Genthate Injection 1MIU (IV)	Each vial contains	Colistimethate Sodium_ 1 MIU-	USP	Biogen Pharma
108055	Genthate Injection **2MIU** (IV)	Each vial contains	Colistimethate Sodium_ 2 MIU eq. to 160mg-	USP	Biogen Pharma
108414	Colmat Dry Powder Injection 1 million IU	Each vial contains	Colistimethate Sodium 1million International Units eq. to_ 80 mg-	USP	Vision Pharmaceuticals Pvt Ltd
108905	Colimethate Powder for Solution for Injection / Infusion 3MIU IV	Each vial contains	Colistimethate Sodium_ 3 MIU eq. to 240mg-	USP Specification	TABROS PHARMA (PVT). LTD.
110206	Nogotex Injection 2MIU IV (Lyophilized Powder for Solution for Injection / Infusion)	Each vial contains	Colistimethate Sodium 2 Million International Units (IU) Eq. to_ 160 mg-	USP Specification	Nabiqasim Industries (Pvt) Ltd.Karachi
110207	Nogotex Injection 3MIU IV (Lyophilized Powder for Solution for Injection / Infusion)	Each vial contains	Colistimethate Sodium 2 Million International Units (IU) Eq. to_ 240 mg-	USP Specification	Nabiqasim Industries (Pvt) Ltd., 17/24 Korangi Industrial Area Karachi., Karachi

Label Claim of same Product Registered in Import:



Innovator Product Label specification and Label Claim USFDA:
Coly-Mycin M Parenteral is supplied in vials containing colistimethate sodium (equivalent to 150 mg colistin base activity per vial) as a white to slightly yellow lyophilized cake.
International Practices:
Specifications and label claims of various product registered world widely has been review and found that those products whose claimed specifications are B.P specifications, their label claim is present in terms of International Units of Colistimethate sodium.as under;
Each vial/ lyophilized vial contains:
colistimethate sodium……. 4.5 million IU
Those products whose claimed specifications are USP, their label claim is presented in terms of Colistin base Activity.as under;
Each vial/lyophilized vial Contains:
Colistimethate sodium (equivalent to) ……150 mg colistin base activity
MHRA in SmPC of Colistimethate Sodium Injection mentions that confusion and medication errors may occur because different expression of dose in term of potency. In TGA, both presentations in terms of International units and Colistin base activity are mentioned (https://www.tga.gov.au/resources/artg/14667.)
COLISTIN LINK colistimethate sodium (equivalent to colistin 150 mg, 4,500,000 IU) powder for injection vial.
Submitted for consideration of Board, Please.

Decision: Registration Board deliberated the matter in details and after through discussion, decided as under;

1. **The concerned label claim of existing registrations of Injection of Colistimethate sodium shall be updated according to approved pharmacopoeial specifications as per following details:**

   - **For U.S.P specification the revised label claim shall be,**

Each vial/lyophilized vial Contains:
Colistimethate sodium (equivalent to) …… (Relative strength of) mg colistin base activity

For example for 1MIU:
Each vial Contains:
Colistimethate sodium equivalent to 34mg Colistin base activity

- **For B.P specification the revised label claim shall be,**
  Each vial/ lyophilized vial contains:
  Colistimethate sodium……. (Relative strength of) million IU

  For example for 1MIU:
  Each vial Contains:
  Colistimethate sodium ……1MIU

2. **Registration Board has further decided to advise registration holders to also mention equivalency of "Colistimetahte sodium (IU)" with "Colistin base activity" in miligrams, on unit carton and label according to relevant strength as the case may be, for examples, as under.**

"Potency of Colistimethate sodium:

1 Million IU	**equivalent to**	**34 mg Colistin base Activity (approximately)**
4.5 Million IU	**equivalent to**	**150 mg Colistin base Activity (approximately)**
9 Million IU	**equivalent to**	**300 mg Colistin Base Activity (approximately)"**

3. **Pharmaceutical firms having already registration of "Colistimethate sodium injection" shall apply to PE&R Division with requisite documents and fee for harmonization of the label claim as per point 1 of above decision.**

Agenda of Evaluator PEC-I

Registration application submitted on form 5F for New Drug Manufacturing License:

Case of New License:

1436.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30772 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 21/07/2022
	The proposed proprietary name / brand name	Throtsin 250mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Azithromycin as dihydrate …….250 mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet (Oral)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Zithromax 250mg Tablet by M/s Pfizer Pharma.
	GMP status of the Finished product manufacturer	New license granted on 22/02/2021 vide letter No.F.2-3/2016-Lic.
	Section approval	Tablet General Section
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceuticals Co., LTD, No.9 xingye street, Shijiazzhuang economic and technological development zone, Hebei province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azithromycin is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (200407021,200407022,200407023)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity etc for drug product and drug susbatnce.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Guolong Pharmaceuticals Co., LTD China		
API Lot No.	220207001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-61	T-62	T-63
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	20-08-2021	20-08-2021	20-08-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1	Provide analytical method verification studies including specificity, precision and accuracy for drug substance performed by drug product manufacturer.	
2	Since the excipients used in the formulation are different from the innovator's / reference product, therefor compatibility studies of excipients with drug substance are required along with the relevant documents.	
3	Details of section 3.2.P.4 have not been provided in the submitted dossier.	
4	Justification is required since you have not performed UNIFORMITY OF DOSAGE UNITS as described in official monograph of USP. Therefore, you are required to submit revised specifications along with the applicable fee.	
5	Submit detail analytical method used for drug product instead of submitted copy of USP monograph.	
6	Provide complete protocols for analytical method verification studies for drug product including details of preparations and concentrations of all the standard solutions in mg/mL used in accuracy and repeatability studies.	
7	Provide COA of reference standard actually used in the product development.	
8	Submit stability study data along with raw data sheets in a proper sequence with separators to segregate the stability data for each time point for all the three batches.	
9	Justification is required since at 3rd month time point of stability studies (accelerated) for batch number T61 and T62 and T63, the retention time and peak of chromatogram is exactly same for sample analysis.	
10	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Record of Digital data logger for temperature and humidity monitoring of both stability chambers.	
10	Provide complete batch manufacturing record along with the calculations for potency adjustment considering the assay value of Azithromycin Dihydrate as per submitted COA.	
11	Provide data of pharmaceutical equivalence and comparative dissolution profile against reference / innovator's product along with the relevant documents.	
12	Scientific justification is required since as per USP monograph of Azithromycin Tablet, the injection volume is 100uL while as per submitted dossier the injection volume Is 20uL. Moreover, provide evidence of use of column oven having capacity to maintain the column temperature at 50°C as per USP requirement.	

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

1437.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30773 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 21/07/2022
	The proposed proprietary name / brand name	Throtsin 500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Azithromycin as dihydrate …….500 mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet (Oral)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Zithromax 500mg Tablet by M/s Pfizer Pharma.
	GMP status of the Finished product manufacturer	New license granted on 22/02/2021 vide letter No.F.2-3/2016-Lic.
	Section approval	Tablet General Section
	Name and address of API manufacturer.	M/s Hebei Guolong Pharmaceuticals Co., LTD, No.9 xingye street, Shijiazzhuang economic and technological development zone, Hebei province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Azithromycin is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (200407021,200407022,200407023)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity etc for drug product and drug susbatnce.

STABILITY STUDY DATA

Manufacturer of API	M/s Hebei Guolong Pharmaceuticals Co., LTD China		
API Lot No.	220207001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-61	T-62	T-63
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	20-08-2021	20-08-2021	20-08-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted

	Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Remarks OF Evaluator:

Sr. No.	Observations	Response by the firm
1	Provide analytical method verification studies including specificity, precision and accuracy for drug substance performed by drug product manufacturer.	
2	Since the excipients used in the formulation are different from the innovator's / reference product, therefor compatibility studies of excipients with drug substance are required along with the relevant documents.	
3	Details of section 3.2.P.4 have not been provided in the submitted dossier.	
4	Justification is required since you have not performed UNIFORMITY OF DOSAGE UNITS as described in official monograph of USP. Therefore, you are required to submit revised specifications along with the applicable fee.	
5	Submit detail analytical method used for drug product instead of submitted copy of USP monograph.	
6	Provide complete protocols for analytical method verification studies for drug product including details of preparations and concentrations of all the standard solutions in mg/mL used in accuracy and repeatability studies.	
7	Provide COA of reference standard actually used in the product development.	
8	Submit stability study data along with raw data sheets in a proper sequence with separators to segregate the stability data for each time point for all the three batches.	
9	Justification is required since at 3rd month time point of stability studies (accelerated) for batch number T61 and T62 and T63, the retention time and peak of chromatogram is exactly same for sample analysis.	
10	Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following: o Reference of previous approval of applications with stability study data of the firm (if any) o Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. o Documents for the procurement of API with approval from DRAP (in case of import). o Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. o Compliance Record of HPLC software 21CFR & audit trail reports on product testing. Record of Digital data logger for temperature and humidity monitoring of both stability chambers.	
10	Provide complete batch manufacturing record along with the calculations for potency adjustment considering the assay value of Azithromycin Dihydrate as per submitted COA.	
11	Provide data of pharmaceutical equivalence and comparative dissolution profile against reference / innovator's product along with the relevant documents.	
12	Scientific justification is required since as per USP monograph of Azithromycin Tablet, the injection volume is 100uL while as per submitted dossier the injection volume Is 20uL. Moreover, provide evidence of use of column oven having capacity to maintain the column temperature at 50°C as per USP requirement.	

Decision: The Board deferred the case for clarification / submission of above mentioned points.

1438.	Name, address of Applicant / Mar keting Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Dry powder injectable (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18405 : 24/06/2022
	Details of fee submitted	PKR 30,000/-: 13/05/2022
	The proposed proprietary name / brand name	Xime-C 200mg/5mL Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL (reconstituted) suspension contains: Cefixime as trihydrate…….200mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cicloxal DS Suspension 200mg/5mL by M/s Grays Pharma
	GMP status	Drug Manufacturing License vide letter No. F.1-5/2017-Lic dated 17/09/2021.
	Section Approval	Oral Dry Powder Suspension (Cephalosporin)
	Name and address of API manufacturer.	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00244/135/2010, 00243/136/2010, 00244/137/2010)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is established against comparator's product Cefspan 200mg/5mL dry suspension mfg by Barrett Hodgson Pakistan, Karachi by performing quality tests (batch number D0037).
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.		
API Lot No.	00243/068/2021		
Description of Pack (Container closure system)	Amber coloured glass bottle closed with aluminium cap.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	10/21	10/21	10/21

Date of Initiation	08/10/2021	08/10/2021	08/10/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP(AD/1998630-530) issued on the basis of inspection conducted on 22/06/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased. Invoice no. 3625 dated 28/09/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The submitted analytical method validations studies for drug substance are performed by drug substance manufacturer, please provide the analytical method verification studies including accuracy, specificity and precision performed by drug product manufacturer.	The firm has submitted analytical method verification report wherein the results for accuracy & recovery, precision and specificity parameters are presented.
2.	Provide in-use stability studies for the applied product.	In-use stability study report is submitted till 14 days after reconstituting the applied product with the diluent. The assay results are within the limits.
3.	Submitted pharmaceutical equivalence studies have been performed against comparator's product while the said studies are required against reference / innovator's product.	The firm has stated that due to easy access of Cefspan dry suspension mfg by Barret Hodgson the pharmaceutical equivalence is performed with the comparator.
4.	Provide reconstitution directions for obtaining the desired dilution that is 200mg/5mL considering total quantity of Cefixime Trihydrate in bottle, since in the submitted dossier the relevant information is not provided. Provide calculation for potency adjustment and final quantity to be dispensed.	Number of doses: 06 Water for reconstitution: 20mL Total volume: 30mL Assay: 99.88% Quantity to be dispensed: 1342
5.	The submitted stability data is till 3rd month time point, please submit stability study data including accelerated and real time stability till 6 months.	submitted.
6	Provide complete batch manufacturing record for the applied product.	Submitted
7	It is not clear whether the stability study data of drug substance is for micronized form or compacted form. Please submit stability study	As per the submitted stability data, it is not evident whether the stability is for micronized or compacted form.

	data of micronized form of Cefixime trihydrate along with the relevant chromatograms.	

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The Board directed the firm to submit stability studies of drug substance according to the conditions of Zone IV-A of 03 batches for micronized Cefixime trihydrate before issuance of registration letter.**

1439.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Dry powder injectable (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18404 : 24/06/2022
	Details of fee submitted	PKR 30,000/-: 13/05/2022
	The proposed proprietary name / brand name	Xime-C 100mg/5mL Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL (reconstituted) suspension contains: Cefixime as trihydrate…….100mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Trispan 100mg/5mL dry suspension mfg by Serpah Pharamceuticals.
	GMP status	Drug Manufacturing License vide letter No. F.1-5/2017-Lic dated 17/09/2021.

	Section Approval	Oral Dry Powder Suspension (Cephalosporin)
	Name and address of API manufacturer.	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Micronized Cefixime is used for the product development. Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00244/135/2010, 00243/136/2010, 00244/137/2010)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is established against comparator's product Cefspan 100mg/5mL dry suspension mfg by Barrett Hodgson Pakistan, Karachi by performing quality tests (batch number D0840).
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.

API Lot No.	00243/068/2021		
Description of Pack (Container closure system)	Amber coloured glass bottle closed with aluminium cap.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	10/21	10/21	10/21
Date of Initiation	06/10/2021	06/10/2021	06/10/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP(AD/1998630-530) issued on the basis of inspection conducted on 22/06/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased. Invoice no. 3625 dated 28/09/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The submitted analytical method validations studies for drug substance are performed by drug substance manufacturer, please provide the analytical method verification studies including accuracy, specificity and precision performed by drug product manufacturer.	The firm has submitted analytical method verification report wherein the results for accuracy & recovery, precision and specificity parameters are presented.
2.	Provide in-use stability studies for the applied product.	In-use stability study report is submitted till 14 days after reconstituting the applied product with the diluent. The assay results are within the limits.
3.	Submitted pharmaceutical equivalence studies have been performed against comparator's product while the said studies are required against reference / innovator's product.	The firm has stated that due to easy access of Cefspan dry suspension mfg by Barret Hodgson the pharmaceutical equivalence is performed with the comparator.
4.	Provide reconstitution directions for obtaining the desired dilution that is 100mg/5mL considering total quantity of Cefixime Trihydrate in bottle, since in the submitted dossier the relevant information is not provided. Provide calculation for potency adjustment and final quantity to be dispensed.	Number of doses: 06 Water for reconstitution: 20mL Total volume: 30mL Assay: 99.88% Quantity to be dispensed: 671mg
5.	The submitted stability data is till 3rd month time point, please submit stability study data including accelerated and real time stability till 6 months.	submitted.
6	Provide complete batch manufacturing record for the applied product.	Submitted
7	It is not clear whether the stability study data of drug substance is for micronized form or compacted form. Please submit stability study data of micronized form of Cefixime trihydrate along with the relevant chromatograms.	As per the submitted stability data, it is not evident whether the stability is for micronized or compacted form.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The Board directed the firm to submit stability studies of drug substance according to the conditions of Zone IV-A of 03 batches for micronized Cefixime trihydrate before issuance of registration letter.**

1440.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Dry powder injectable (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22079 : 08/08/2022
	Details of fee submitted	PKR 30,000/-: 13/05/2022
	The proposed proprietary name / brand name	Xime-C 400mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Cefixime as trihydrate…..400mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cefspan 400mg capsule by M/s Barret Hodgson.
	GMP status	Drug Manufacturing License vide letter No. F.1-5/2017-Lic dated 17/09/2021.
	Section Approval	Capsule (Cephalosporin)
	Name and address of API manufacturer.	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Compacted Cefixime trihydrate is used for product development.Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence studies have been performed against Cefim 400mg capsule mfg by Hilton Pharma by performing all the quality tests. Comparative Dissolution Profile is submitted against the same brand in all the three media that is 0.1NHCl, Phosphate Buffer and Acetate Buffer.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.		
API Lot No.	00244/067/2021		
Description of Pack (Container closure system)	Alu-alu blister packed in secondary unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Cap	1000 Cap	1000 Cap
Manufacturing Date	10/21	10/21	10/21
Date of Initiation	10/10/2021	10/10/2021	10/10/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP(AD/1998630-530) issued on the basis of inspection conducted on 22/06/2020.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The submitted analytical method validations studies for drug substance are performed by drug substance manufacturer, please provide the analytical method verification studies including accuracy, specificity and precision performed by drug product manufacturer.	Submitted.
2.	Provide documents confirming the purchase of API.	Copy of invoice no. 3623 dated 28/09/2021.
3.	Submitted pharmaceutical equivalence studies have been performed against comparator's product while the said studies are required against reference / innovator's product.	*Due to easy availability of the comparator's product, the studies have been performed against comparator's product.*
4.	Provide detail of reference standard along with the certificate of analysis.	The firm has submitted relevant details of reference standard along with the submission of COA (Batch number : WS/Cefixime/075).
5.	The submitted stability data is till 3rd month time point, please submit stability study data including accelerated and real time stability till 6 months.	Submitted.
6	Provide complete batch manufacturing record for the applied product.	Submitted. Dispensed Quantity: 447mg While considering assay value of cefixime (as per submitted COA) the actually quantity that should have been dispensed is 452mg.
7	It is not clear whether the stability study data of drug substance is for micronized form or compacted form. Please submit stability study data of compacted form of Cefixime trihydrate along with the relevant chromatograms.	As per the submitted stability data, it is not evident whether the stability is for micronized or compacted form.
8	Justification is required since the applied product is developed according to Japanese Pharmacopoeial monograph which is for 100mg and 50mg capsule. Moreover, Drug Regulatory Authority of Pakistan has published the monograph for 400mg and 200mg Cefixime as Trihydrate capsule vide	The firm has stated that the initial stability study was according to JP monograph while 6th month stability studies was performed according to the monograph approved in 313rd meeting of RB. However, the firm has not submitted any supporting document.

	notification No.F.14-1/2022-PEC dated 14th March, 2022.	
9	Provide documents confirming the purchase of API.	Copy of invoice no. 3623 dated 28/09/2021.

Decision: Approved with Manufacturer's specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will dispense the drug substance based upon actual potency determined during drug substance analysis, for commercial manufacturing of applied drug product.**
- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **The Board further decided that the applicant will submitted Pharmaceutical Equivalence and comparative dissolution studies against Cefspan Capsule by M/s Barret Hodgson before issuance of registration letter.**

1441.	Name, address of Applicant / Marketing Authorization Holder	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Name, address of Manufacturing site.	M/s Qadir Pharmaceuticals, Veerum Fateh Garh Sahuwala Road, Sialkot.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000944) by way of formulation dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 17-09-2021 which specifies Dry powder injectable (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20876 : 12/08/2022
	Details of fee submitted	PKR 30,000/-: 08/06/2022
	The proposed proprietary name / brand name	Xime-C 200mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Cefixime as trihydrate…..200mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cefim 200mg capsule by M/s Barret Hodgson.

	GMP status	Drug Manufacturing License vide letter No. F.1-5/2017-Lic dated 17/09/2021.
	Section Approval	Capsule (Cephalosporin)
	Name and address of API manufacturer.	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Compacted Cefixime trihydrate is used for product development.Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months • Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence studies have been performed against Cefim 200mg capsule mfg by Hilton Pharma by performing all the quality tests. Comparative Dissolution Profile is submitted against the same brand in all the three media that is 0.1NHCl, Phosphate Buffer and Acetate Buffer.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	Pharmagen Ltd. Kot Nabi Buksh Wala 34-Km, Ferozepur Road, Lahore.		
API Lot No.	00244/067/2021		
Description of Pack (Container closure system)	Alu-alu blister packed in secondary unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 Cap	1000 Cap	1000 Cap
Manufacturing Date	10/21	10/21	10/21
Date of Initiation	19/10/2021	10/10/2021	10/10/2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP(AD/1998630-530) issued on the basis of inspection conducted on 22/06/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The submitted analytical method validations studies for drug substance are performed by drug substance manufacturer, please provide the analytical method verification studies including accuracy, specificity and precision performed by drug product manufacturer.	Submitted.
2.	Provide documents confirming the purchase of API.	Copy of invoice no. 3623 dated 28/09/2021.
3.	Submitted pharmaceutical equivalence studies have been performed against comparator's product while the said studies are required against reference / innovator's product.	*Due to easy availability of the comparator's product, the studies have been performed against comparator's product.*

4.	Provide detail of reference standard along with the certificate of analysis.	The firm has submitted relevant details of reference standard along with the submission of COA (Batch number : WS/Cefixime/075).
5.	The submitted stability data is till 3rd month time point, please submit stability study data including accelerated and real time stability till 6 months.	Submitted.
6	Provide complete batch manufacturing record for the applied product.	Submitted. Dispensed Quantity: 225mg While considering assay value of cefixime (as per submitted COA) the actually quantity that should have been dispensed is 226.32mg.
7	It is not clear whether the stability study data of drug substance is for micronized form or compacted form. Please submit stability study data of compacted form of Cefixime trihydrate along with the relevant chromatograms.	As per the submitted stability data, it is not evident whether the stability is for micronized or compacted form.
8	Justification is required since the applied product is developed according to Japanese Pharmacopoeial monograph which is for 100mg and 50mg capsule. Moreover, Drug Regulatory Authority of Pakistan has published the monograph for 400mg and 200mg Cefixime as Trihydrate capsule vide notification No.F.14-1/2022-PEC dated 14th March, 2022.	The firm has stated that the initial stability study was according to JP monograph while 6th month stability studies was performed according to the monograph approved in 313rd meeting of RB. However, the firm has not submitted any supporting document.
9	Provide documents confirming the purchase of API.	Copy of invoice no. 3623 dated 28/09/2021.

Decision: Approved with Manufacturer's specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will dispense the drug substance based upon actual potency determined during drug substance analysis, for commercial manufacturing of applied drug product.**
- **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **The Board further decided that the applicant will submitted Pharmaceutical Equivalence and comparative dissolution studies against Cefspan Capsule by M/s Barret Hodgson before issuance of registration letter.**

1442.	Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker (pvt) Ltd., 45km, Dina Nath, Multan road, Lahore.
	Name, address of Manufacturing site.	M/s May & Baker (pvt) Ltd., 45km, Dina Nath, Multan road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30788 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 31/10/2022
	The proposed proprietary name / brand name	Colmate 4.5 MIU powder for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate as sodium ……..4.5 MIU
	Pharmaceutical form of applied drug	White Lyophilized Powder for solution for IV injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Colitin Link 4,500,000 IU powder for injection vial, TGA Australia approved.
	For generic drugs (me-too status)	Colistim 4.5MIU by Biocare Pharmaceutica,
	GMP status of the Finished product manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Section approval	Dry Powder Vial Section (General)
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China. Copy of GMP certificate no. FJ200003 valid till 21/09/2022 issued by Fujian Food and Drug Administration China..
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls,

		impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CMS1707001, CMS1707002, CMS1707003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method validation / verification studies have submitted including accuracy/recovery, precision, specificity, , system suitability etc for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.		
API Lot No.	CMS2106002		
Description of Pack (Container closure system)	Type I glass vial packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRL01	TRL02	TRL03
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	03-2022	03	2022
Date of Initiation	10-03-2022	10	03
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. FJ200003 valid till 21/09/2022 issued by Fujian Food and Drug Administration China..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of clearance certificate no. 2761/2021-ADC(I&E) dated 16/08/2021 issued for M/s Vision Pharmaceuticals Islamabad. The material has been borrowed from M/s Vision Pharmaceuticals.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**N/A**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Sr. No.	Observations	Response
1	Provide documents of approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. FJ200003 valid till 21/09/2022 issued by Fujian Food and Drug Administration China..
2	Provide analytical method verification studies (including accuracy, specificity and precision) for drug substance performed by drug product manufacturer.	Submitted. Test results for specificity is not provided.
3	Provide pharmaceutical equivalence studies against innovator's / reference product by performing all the quality tests.	Not submitted
4	Provide documents confirming import of drug substance (invoice, clearance certificate etc) attested from DRAP.	Copy of clearance certificate no. 2761/2021-ADC(I&E) dated 16/08/2021 issued for M/s Vision Pharmaceuticals Islamabad. The material has been borrowed from M/s Vision Pharmaceuticals. The firm has submitted loan letter for the API (Colistimethate Sdoium) from M/s Vision Pharmaceuticals ref. no. V/2022/787 dated 14/03/2022.
5	Provide exact date of initiation of stability studies and detail of batch sizes.	Submitted.
6	Provide stability summary sheets containing results till 6 months along with raw data sheets for accelerated and real time stability. • The firm has not submitted the stability summary sheets. • The data submitted is not comprehendible.	

Strength	Accelerated (%)			Real time (%)		
	0	3	6	0	3	6
1 MIU	103.78	102.2	102.07	102.19	102.4	103.01

		103.33	100.53	101.42	105.55	101.48	102.81
		102.8	100.53	105.53	101.21	101.48	102.41
	2 MIU	103.78	102.2	102.07	102.19	102.4	103.01
		103.33	100.53	101.42	105.55	101.48	102.81
		102.8	100.53	105.53	101.21	101.48	102.41
	4.5 MIU	103.78	102.2	102.07	102.19	102.4	103.01
		103.33	100.53	101.42	105.55	101.48	102.81
		102.8	100.53	105.53	101.21	101.48	102.41

Decision: The Board was apprised as under:

- **As per submitted stability data, the assay results of accelerated and real time stability studies at initial time points are different while the results should be the same for all the three batches.**
- **The results of assay for all the three batches are exactly same on respective time points throughout the stability studies which is not practically possible.**

The Board decided to defer the case for clarification / scientific justification of the above mentioned observations along with the submission of Pharmaceutical Equivalence studies against the reference / innovator's product.

1443.	Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker (pvt) Ltd., 45km, Dina Nath, Multan road, Lahore.
	Name, address of Manufacturing site.	M/s May & Baker (pvt) Ltd., 45km, Dina Nath, Multan road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30787 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 30/10/2022
	The proposed proprietary name / brand name	Colmate 2 MIU powder for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate as sodium……..2 MIU
	Pharmaceutical form of applied drug	White Lyophilized Powder for solution for IV injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Colistim 2MIU by M/s Biopharmaseutica.
	GMP status of the Finished product manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Section approval	Dry Powder Vial Section (General)

	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CMS1707001, CMS1707002, CMS1707003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method validation / verification studies have submitted including accuracy/recovery, precision, specificity, , etc for drug substance and drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.		
API Lot No.	CMS2106002		
Description of Pack (Container closure system)	Type I glass vial packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRL01	TRL02	TRL03
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	09-03-2022	09-03-2022	09-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. FJ200003 valid till 21/09/2022 issued by Fujian Food and Drug Administration China..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of clearance certificate no. 2761/2021-ADC(I&E) dated 16/08/2021 issued for M/s Vision Pharmaceuticals Islamabad. The material has been borrowed from M/s Vision Pharmaceuticals.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**N/A**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

1	Provide documents of approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. FJ200003 valid till 21/09/2022 issued by Fujian Food and Drug Administration China..
2	Provide analytical method verification studies (including accuracy, specificity and precision) for drug substance performed by drug product manufacturer.	Submitted. Test results for specificity is not provided.
3	Provide pharmaceutical equivalence studies against innovator's / reference product by performing all the quality tests.	Not submitted

4	Provide documents confirming import of drug substance (invoice, clearance certificate etc) attested from DRAP.	Copy of clearance certificate no. 2761/2021-ADC(I&E) dated 16/08/2021 issued for M/s Vision Pharmaceuticals Islamabad. The material has been borrowed from M/s Vision Pharmaceuticals. The firm has submitted loan letter for the API (Colistimethate Sdoium) from M/s Vision Pharmaceuticals ref. no. V/2022/787 dated 14/03/2022.
5	Provide exact date of initiation of stability studies and detail of batch sizes.	Submitted.
6	Provide stability summary sheets containing results till 6 months along with the all the chromatograms along with raw data sheets for accelerated and real time stability. • The firm has not submitted the stability summary sheets. • The data submitted is not comprehendible.	

Strength	Accelerated (%)			Real time (%)		
	0	3	6	0	3	6
1 MIU	103.78	102.2	102.07	102.19	102.4	103.01
	103.33	100.53	101.42	105.55	101.48	102.81
	102.8	100.53	105.53	101.21	101.48	102.41
2 MIU	103.78	102.2	102.07	102.19	102.4	103.01
	103.33	100.53	101.42	105.55	101.48	102.81
	102.8	100.53	105.53	101.21	101.48	102.41
4.5 MIU	103.78	102.2	102.07	102.19	102.4	103.01
	103.33	100.53	101.42	105.55	101.48	102.81
	102.8	100.53	105.53	101.21	101.48	102.41

Decision: The Board was apprised as under:

- **As per submitted stability data, the assay results of accelerated and real time stability studies at initial time points are different while the results should be the same for all the three batches.**
- **The results of assay for all the three batches are exactly same on respective time points throughout the stability studies which is not practically possible.**

The Board decided to defer the case for clarification / scientific justification of the above mentioned observations along with the submission of Pharmaceutical Equivalence studies against the reference / innovator's product.

1444.	Name, address of Applicant / Marketing Authorization Holder	M/s May & Baker (pvt) Ltd., 45km, Dina Nath, Multan road, Lahore.
	Name, address of Manufacturing site.	M/s May & Baker (pvt) Ltd., 45km, Dina Nath, Multan road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30039 dated 24/10/2022
	Details of fee submitted	PKR 30,000/-: dated 18/10/2022

	The proposed proprietary name / brand name	Colmate 1 MIU powder for injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate as sodium……..1 MIU
	Pharmaceutical form of applied drug	White Lyophilized Powder for solution for IV injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Colistim 1MIU by Biocare Pharmaceutica,
	GMP status of the Finished product manufacturer	DML issued vide letter No.F.1-10/2019-Lic dated 29/04/2022.
	Section approval	Dry Powder Vial Section (General)
	Name and address of API manufacturer.	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CMS1707001, CMS1707002, CMS1707003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method validation / verification studies have submitted including accuracy/recovery, precision, specificity, , system suitability etc for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd., No. 8. Nangang road Jiangyin Industrial Concentration zone, Fuqing, Fuzhou city, Fujian province, China.		
API Lot No.	CMS2106002		
Description of Pack (Container closure system)	Type I glass vial packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRL01	TRL02	TRL03
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	08-03-2022	08-03-2022	08-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. FJ200003 valid till 21/09/2022 issued by Fujian Food and Drug Administration China..
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of clearance certificate no. 2761/2021-ADC(I&E) dated 16/08/2021 issued for M/s Vision Pharmaceuticals Islamabad. The material has been borrowed from M/s Vision Pharmaceuticals. The firm has submitted loan letter for the API (Colistimethate Sdoium) from M/s vision Pharmaceuticals ref. no. V/2022/787 dated 14/03/2022.ocument related to borrowing of API.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**N/A**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator-I:

1	Provide documents of approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. FJ200003 valid till 21/09/2022 issued by Fujian Food and Drug Administration China..
2	Provide analytical method verification studies (including accuracy, specificity and precision) for drug substance performed by drug product manufacturer.	Submitted. Test results for specificity is not provided.
3	Provide pharmaceutical equivalence studies against innovator's / reference product by performing all the quality tests.	Not submitted
4	Provide documents confirming import of drug substance (invoice, clearance certificate etc) attested from DRAP.	Copy of clearance certificate no. 2761/2021-ADC(I&E) dated 16/08/2021 issued for M/s Vision Pharmaceuticals Islamabad. The material has been borrowed from M/s Vision Pharmaceuticals.
5	Provide exact date of initiation of stability studies and detail of batch sizes.	Submitted.
6	Provide stability summary sheets containing results till 6 months along with the all the chromatograms along with raw data sheets for accelerated and real time stability. • The firm has not submitted the stability summary sheets. • The data submitted is not comprehendible.	

Strength	**Accelerated (%)**			**Real time (%)**		
	0	**3**	**6**	**0**	**3**	**6**
1 MIU	103.78	102.2	102.07	102.19	102.4	103.01
	103.33	100.53	101.42	105.55	101.48	102.81
	102.8	100.53	105.53	101.21	101.48	102.41
2 MIU	103.78	102.2	102.07	102.19	102.4	103.01
	103.33	100.53	101.42	105.55	101.48	102.81
	102.8	100.53	105.53	101.21	101.48	102.41
4.5 MIU	103.78	102.2	102.07	102.19	102.4	103.01
	103.33	100.53	101.42	105.55	101.48	102.81
	102.8	100.53	105.53	101.21	101.48	102.41

Decision: The Board was apprised as under:

- **As per submitted stability data, the assay results of accelerated and real time stability studies at initial time points are different while the results should be the same for all the three batches.**
- **The results of assay for all the three batches are exactly same on respective time points throughout the stability studies which is not practically possible.**

The Board decided to defer the case for clarification / scientific justification of the above mentioned observations along with the submission of Pharmaceutical Equivalence studies against the reference / innovator's product.

1445.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27639 dated 29/09/2022
	Details of fee submitted	PKR 30,000/-: dated 19/09/2022
	The proposed proprietary name / brand name	Amloflow tablets 10mg+160mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as Besylate…….10mg Valsartan……160mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Calcium channel blocker/Angiotensin receptor blocker
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	A per SRO
	The status in reference regulatory authorities	Exforge Tablets (5/160, 10/160, 5/320, 10/320)by M/s Novartis Pharmaceuticals Corp. (USFDA Approved)
	For generic drugs (me-too status)	Amstan 10mg/160mg by M/s Getz Pharma
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Section approval	Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma Chem. Plot no. 7407, Behind Lyka Lab, GIDC Ind. Estate, Ankleshwar-393 002, Dist. Bharuch Gujarat, India. Copy of GMP certificate No. S-GMP & GLP/22053332 valid till 26/05/2024 issued by Food & Drugs Control Administration, India. **Valsartan:** Zhuhai Rundu Pharaceutical Co., Ltd., No. 6, North Airport road, Sanzo town, Jinwan district, Zhuhai City, Guangdong Province-519041, China.

		Copy of GMP certificate no. GD20190988 valid till 10/04/2024 issued by CFDA, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Amlodipine:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: (AMB/002/01/14, AMB/003/02/14, AMB/004/02/14) **Valsartan:** Real time: 30˚C ± 2˚C / 75% ± 5%RH 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: (67819030611, 67819030612, 67819030613)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence is established against Exforge Tablet 10-160mg by M/s Novartis Pharmaceutical, USFDA Approved by performing all the quality tests (Batch number: BAUR9). Comparative dissolution profile is submitted against the same brand in all the three media that is 0.1N HCl, Phosphate Buffer and Acetate Buffer.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.
STABILITY STUDY DATA		
Manufacturer of API	**Amlodipine:** M/s Prudence Pharma Chem. Plot no. 7407, Behind Lyka Lab, GIDC Ind. Estate, Ankleshwar-393 002, Dist. Bharuch Gujarat, India. **Valsartan:**	

	M/s Zhuhai Rundu Pharmaceutical Co., Ltd., No. 6, North Airport road, Sanzo town, Jinwan district, Zhuhai City, Guangdong Province-519041, China.		
API Lot No.	Amlodipine: AMB/143/09/21 Valsartan: 67821040608		
Description of Pack (Container closure system)	Alu-alu blister packed in secondary unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T012	T019	T020
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	01/04/2022	01/04/2022	01/04/2022
Date of Initiation	26/04/2022	26/04/2022	26/04/2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amlodipine:** Copy of GMP certificate No. S-GMP & GLP/22053332 valid till 26/05/2024 issued by Food & Drugs Control Administration, India. **Valsartan:** Copy of GMP certificate no. GD20190988 valid till 10/04/2024 issued by CFDA, China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Amlodipine (AMB/143/09/21: Copy of invoice number EP/21-22/397 dated 04/12/2021 cleared on 28/12/2021. Valsartan (67821040608): Copy of invoice number RD2021102509-1 dated 09/11/2021 cleared on 29/11/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator-I:

Observations	**Response**

The submitted stability data is till 3rd month time point, please submit stability studies till 6 months for 3 batches.	Stability data till 6th month time point is submitted.
Provide documents confirming import of API (Amlodipine and Valsartan) endorsed from DRAP.	Amlodipine (AMB/143/09/21): Copy of invoice number EP/21-22/397 dated 04/12/2021 cleared on 28/12/2021. Valsartan (67821040608): Copy of invoice number RD2021102509-1 dated 09/11/2021 cleared on 29/11/2021
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	submitted
Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required.	submitted
COAs of Valsartan and Amlodipine for the batches used for the product development from drug product manufacturer as well as from drug substance manufacturer are required.	Submitted. Amlodipine: AMB/143/09/21 Valsartan: 67821040608
Submit detail of primary container closure for the applied product.	Alu-Alu foil blister and secondary container closure is unit carton with pack size of 3×7's.
Provide complete batch manufacturing record for the applied product with the calculations for potency adjustment.	The firm has submitted complete batch manufacturing record.

Decision: Approved.

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

1446.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27127 dated 29/09/2022
	Details of fee submitted	PKR 30,000/-: dated 19/09/2022
	The proposed proprietary name / brand name	**Amloflow tablets 5mg+80mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as Besylate…….5mg Valsartan……80mg

	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Calcium channel blocker/Angiotensin receptor blocker
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	A per SRO
	The status in reference regulatory authorities	Apo 5/80mg Tablet by M/s Apotex Pty ltd, TGA Australia Approved.
	For generic drugs (me-too status)	Amstan 5mg/80mg by M/s Getz Pharma
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Section approval	Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma Chem. Plot no. 7407, Behind Lyka Lab, GIDC Ind. Estate, Ankleshwar-393 002, Dist. Bharuch Gujarat, India. Copy of GMP certificate No. S-GMP & GLP/22053332 valid till 26/05/2024 issued by Food & Drugs Control Administrtation, India. **Valsartan:** Zhuhai Rundu Pharaceutical Co., Ltd., No. 6, North Airport road, Sanzo town, Jinwan district, Zhuhai City, Guangdong Province-519041, China. Copy of GMP certificate no. GD20190988 vaid till 10/04/2024 issued by CFDA, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Amlodipine:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 6 months Batches: (AMB/002/01/14, AMB/003/02/14, AMB/004/02/14)

		Valsartan: Real time: 30°C ± 2°C / 75% ± 5%RH 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH 6 months Batches: (67819030611, 67819030612, 67819030613)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence is established against Exforge Tablet 5-80mg by M/s Novartis Pharmaceutical, EMA Approved by performing all the quality tests (Batch number: BCAL6) Comparative dissolution profile is submitted against the same brand in all the three media that is 0.1N HCl, Phosphate Buffer and Acetate Buffer.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.

STABILITY STUDY DATA

Manufacturer of API	**Amlodipine:** M/s Prudence Pharma Chem. Plot no. 7407, Behind Lyka Lab, GIDC Ind. Estate, Ankleshwar-393 002, Dist. Bharuch Gujarat, India. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co., Ltd., No. 6, North Airport road, Sanzo town, Jinwan district, Zhuhai City, Guangdong Province-519041, China.		
API Lot No.	Amlodipine: AMB/143/09/21 Valsartan: 67821040608		
Description of Pack (Container closure system)	Alu-alu blister packed in secondary unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T003	T007	T020
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	25/03/2022	29/03/2022	31/03/2022
Date of Initiation	15/04/2022	15/04/2022	15/04/2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amlodipine:** Copy of GMP certificate No. S-GMP & GLP/22053332 valid till 26/05/2024 issued by Food & Drugs Control Administrtation, India. **Valsartan:** Copy of GMP certificate no. GD20190988 vaid till 10/04/2024 issued by CFDA, China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Amlodipine (AMB/143/09/21): Copy of invoice number EP/21-22/397 dated 04/12/2021 cleared on 28/12/2021. Valsartan (67821040608): Copy of invoice number RD2021102509-1 dated 09/11/2021 cleared on 29/11/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator-I:

Observations	**Response**
The submitted stability data is till 3rd month time point, please submit stability studies till 6 months for 3 batches.	Stability data till 6th month time point is submitted.
Provide documents confirming import of API (Amlodipine and Valsartan) endorsed from DRAP.	Amlodipine (AMB/143/09/21): Copy of invoice number EP/21-22/397 dated 04/12/2021 cleared on 28/12/2021. Valsartan (67821040608): Copy of invoice number RD2021102509-1 dated 09/11/2021 cleared on 29/11/2021
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	submitted
Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required.	submitted
COAs of Valsartan and Amlodipine for the batches used for the product development from drug product manufacturer as well as from drug substance manufacturer are required.	Submitted. Amlodipine: AMB/143/09/21 Valsartan: 67821040608
Submit detail of primary container closure for the applied product.	Alu-Alu foil blister and secondary container closure is unit carton with pack size of 3×7's.
Provide complete batch manufacturing record for the applied product with the calculations for potency adjustment.	The firm has submitted complete batch manfuatcruing record.

The reference product that is Exforge against which CDP and pharmaceutical equivalence studies have been performed is approved USFDA in the strengths (5/160, 10/160, 5/320, 10/320) but as per submitted dossier, the said studies have been performed against Exforge tablet 5/80mg which is not approved by USFDA, please clarify.	The firm has stated that the strength 5/80mg is approved by EMA and marketed by M/s Novartis.

Decision: Approved.

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

1447.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27906 dated 27/09/2022
	Details of fee submitted	PKR 30,000/-: dated 19/09/2022
	The proposed proprietary name / brand name	Amloflow tablets 5mg+160mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Amlodipine as Besylate…….5mg Valsartan……160mg
	Pharmaceutical form of applied drug	Immediate release film coated tablet
	Pharmacotherapeutic Group of (API)	Calcium channel blocker/Angiotensin receptor blocker
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's
	Proposed unit price	A per SRO
	The status in reference regulatory authorities	Exforge Tablets (5/160, 10/160, 5/320, 10/320)by M/s Novartis Pharmaceuticals Corp. (USFDA Approved)
	For generic drugs (me-too status)	Amstan 5mg/160mg by M/s Getz Pharma
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.

	Section approval	Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved
	Name and address of API manufacturer.	**Amlodipine:** M/s Prudence Pharma Chem. Plot no. 7407, Behind Lyka Lab, GIDC Ind. Estate, Ankleshwar-393 002, Dist. Bharuch Gujarat, India. Copy of GMP certificate No. S-GMP & GLP/22053332 valid till 26/05/2024 issued by Food & Drugs Control Administrtation, India. **Valsartan:** Zhuhai Rundu Pharaceutical Co., Ltd., No. 6, North Airport road, Sanzo town, Jinwan district, Zhuhai City, Guangdong Province-519041, China. Copy of GMP certificate no. GD20190988 vaid till 10/04/2024 issued by CFDA, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Amlodipine:** Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH 6 months Batches: (AMB/002/01/14, AMB/003/02/14, AMB/004/02/14) **Valsartan:** Real time: 30°C ± 2°C / 75% ± 5%RH 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH 6 months Batches: (67819030611, 67819030612, 67819030613)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence is established against Exforge Tablet 5-160mg by M/s Novartis Pharmaceutical, USFDA Approved by performing all the quality tests (Batch number: (BCDV8).

		Comparative dissolution profile is submitted against the same brand in all the three media that is 0.1N HCl, Phosphate Buffer and Acetate Buffer.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	**Amlodipine:** M/s Prudence Pharma Chem. Plot no. 7407, Behind Lyka Lab, GIDC Ind. Estate, Ankleshwar-393 002, Dist. Bharuch Gujarat, India. **Valsartan:** M/s Zhuhai Rundu Pharmaceutical Co., Ltd., No. 6, North Airport road, Sanzo town, Jinwan district, Zhuhai City, Guangdong Province-519041, China.		
API Lot No.	Amlodipine: AMB/143/09/21 Valsartan: 67821040608		
Description of Pack (Container closure system)	Alu-alu blister packed in secondary unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T011	T021	T022
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	30/03/2022	11/04/2022	11/04/2022
Date of Initiation	26/04/2022	26/04/2022	26/04/2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Amlodipine:** Copy of GMP certificate No. S-GMP & GLP/22053332 valid till 26/05/2024 issued by Food & Drugs Control Administrtation, India. **Valsartan:** Copy of GMP certificate no. GD20190988 vaid till 10/04/2024 issued by CFDA, China.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Amlodipine (AMB/143/09/21): Copy of invoice number EP/21-22/397 dated 04/12/2021 cleared on 28/12/2021. Valsartan (67821040608): Copy of invoice number RD2021102509-1 dated 09/11/2021 cleared on 29/11/2021

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

Remarks of Evaluator-I:

Observations	**Response**
The submitted stability data is till 3rd month time point, please submit stability studies till 6 months for 3 batches.	Stability data till 6th month time point is submitted.
Provide documents confirming import of API (Amlodipine and Valsartan) endorsed from DRAP.	Amlodipine (AMB/143/09/21): Copy of invoice number EP/21-22/397 dated 04/12/2021 cleared on 28/12/2021. Valsartan (67821040608): Copy of invoice number RD2021102509-1 dated 09/11/2021 cleared on 29/11/2021
Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	submitted
Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required.	submitted
COAs of Valsartan and Amlodipine for the batches used for the product development from drug product manufacturer as well as from drug substance manufacturer are required.	Submitted. Amlodipine: AMB/143/09/21 Valsartan: 67821040608
Submit detail of primary container closure for the applied product.	Alu-Alu foil blister and secondary container closure is unit carton with pack size of 3×7's.
Provide complete batch manufacturing record for the applied product with the calculations for potency adjustment.	The firm has submitted complete batch manufacturing record.

Decision: Approved.

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

1448.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30339 dated 26/10/2022
	Details of fee submitted	PKR 30,000/-: dated 17-10-2022
	The proposed proprietary name / brand name	Flemox Suspension 250
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml (reconstituted) contains: Amoxicillin (as trihydrate)……. 250mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Penicillin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's (60ml, 90ml, 100ml, 120ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Amoxilite oral suspension by M/s PDH Laboratories Reg.# 040211 Oximox suspension by CSH
	GMP status of the Finished product manufacturer	New license granted on 14/09/2021.
	Section approval	Oral Dry Powder for Suspension (penicillin)
	Name and address of API manufacturer.	Pharmagen Limited Address: Kot Nabi Bukshwala 34 Km-Ferozpur Road, Lahore, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.

	Stability studies	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00013/210/2009, 00013/211/2009, 00013/212/2009)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Amoxil by M/s GSK (Batch # SM6W) by performing quality tests.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Address: Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.		
API Lot No.	00002/070/2021 (micronized)		
Description of Pack (Container closure system)	Flemox Suspension 125 packed in Amber colored Glass bottle packaging that is further packed in cardboard unit carton along with patient leaflet insert.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1666 bottles	1666 bottles	1666 Bottles
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	04-04-2022	04-04-2022	04-04-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. 129/2020-DRAP(AD/1998630-530) issued on the basis of inspection conducted on 22/06/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchased. Invoice submitted. Invoice number 698 dated 11/10/2021.

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

Remarks of Evaluator-I:

Sr. No.	Observations	Response
1	Provide COA of relevant batch on Amoxicillin which is used for product development from drug substance and drug product manufacturer.	The firm has submitted COA of relevant batch used for development of the applied product is submitted. Batch number : 000120/390/2021
2	Analytical method verification studies for drug substance including specificity, accuracy and precision performed by drug product manufacturer are required.	Submitted. System suitability, specificity, accuracy, precision.
3	Excipients used in the applied formulation are different from the excipient used by the innovator, therefore, you are required to submit compatibility studies of excipients with the drug substance. The reference product that is Amoxil Suspension MHRA Approved has different excipient as that of the applied product. Therefore, compatibility studies of excipient are required.	The firm has stated that the excipients of the applied formulation are similar to the generic products approved by MHRA of M/s Cheliona Healthcare Limited.
3	Provide in-use stability study of the applied product.	In-use stability after reconstitution is submitted till 14 days.
4	Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted.
5	Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
6	Submit complete batch manufacturing record for the applied product.	The firm has submitted complete batch manufacturing record for the applied product.

Decision: Approved.

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

1449.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30340 dated 26/10/2022
	Details of fee submitted	PKR 30,000/-: dated 17-10-2022
	The proposed proprietary name / brand name	**Flemox Suspension 125**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml (reconstituted) contains: Amoxicillin (as trihydrate)……. 125mg
	Pharmaceutical form of applied drug	Powder for oral suspension
	Pharmacotherapeutic Group of (API)	Penicillin
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's (60ml, 90ml, 100ml, 120ml)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Amoxilite oral suspension by M/s PDH Laboratories Oximox suspension by CSH
	GMP status of the Finished product manufacturer	New license granted on 14/09/2021.
	Section approval	Oral Dry Powder for Suspension (penicillin)
	Name and address of API manufacturer.	Pharmagen Limited Address: Kot Nabi Bukshwala 34 Km-Ferozpur Road, Lahore, Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference

		standards, container closure system and stability studies of drug substance.
	Stability studies	• Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00013/210/2009, 00013/211/2009, 00013/212/2009)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader by M/s GSK (Batch # SM6W) by performing quality tests.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited Address: Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.		
API Lot No.	00003/054/2021 (compacted) 00002/070/2021 (micornized		
Description of Pack (Container closure system)	Flemox Suspension 250 packed in Amber colored Glass bottle packaging that is further packed in cardboard unit carton along with patient leaflet insert.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	1666 Vial	1666 Vial	1666 Vial
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	14-03-2022	15-03-2022	16-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. 129/2020-DRAP(AD/1998630-530) issued on the basis of inspection conducted on 22/06/2020.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchased. Invoice submitted. Invoice number 698 dated 11/10/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator-I:

Sr. No.	Observations	Response
1	Provide COA of relevant batch on Amoxicillin which is used for product development from drug substance and drug product manufacturer.	The firm has submitted COA of relevant batch used for development of the applied product is submitted. Batch number : 000120/390/2021
2	Analytical method verification studies for drug substance including specificity, accuracy and precision performed by drug product manufacturer are required.	Submitted. System suitability, specificity, accuracy, precision.
3	Excipients used in the applied formulation are different from the excipient used by the innovator, therefore, you are required to submit compatibility studies of excipients with the drug substance. The reference product that is Amoxil Suspension MHRA Approved has different excipient as that of the applied product. Therefore, compatibility studies of excipient are required.	The firm has stated that the excipients of the applied formulation are similar to the generic products approved by MHRA of M/s Cheliona Healthcare Limited.
3	Provide in-use stability study of the applied product.	In-use stability after reconstitution is submitted till 14 days.
4	Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted.
5	Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted.
6	Submit complete batch manufacturing record for the applied product.	The firm has submitted complete batch manufacturing record for the applied product.
7	Provide pharmaceutical equivalence performed against reference / innovator's product by performing all the quality tests.	The firm has submitted COA of relevant batch used for development of the applied product is submitted. Batch number : 000120/390/2021

Decision: Approved.

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

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

Case of New Section:

1450.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Name, address of Manufacturing site.	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27905 dated 03/10/2022
	Details of fee submitted	PKR 30,000/-: dated 05/04/2022
	The proposed proprietary name / brand name	**PD-Cof Syrup 120mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Aminophylline anhydrous……..….32mg 8 45ERDSZ HCl……...8mg Ammonium Chloride…..30mg
	Pharmaceutical form of applied drug	Vlear light brown solution with caramel Flavor
	Pharmacotherapeutic Group of (API)	Anti-tussive
	Reference to Finished product specifications	Manufacturer’s specifications
	Proposed Pack size	1’s (120mL)
	Proposed unit price	As per
	The status in reference regulatory authorities	
	For generic drugs (me-too status)	Hydryllin Syrup 120mL by M/s Searle Pakistan ltd.,
	GMP status of the Finished product manufacturer	Inspection report dated 03/01/2022 & 04/01/2022 is submitted. The panel recommended renewal of DML.
	Section approval	Oral Liquid Section (General) vide letter no.F.1-1/86-Lic(Vol-V) dated 7th June, 2022.
	Name and address of API manufacturer.	**Diphenhydramine HCl:** M/s Qidong Dongyue Pharmaceutical Co., Ltd., No. 268 Shanghai road, Binjiang fine chemical industry zone, Qidong City, Jiangsu province, China. GMP certificate no. JS20160535 valid till 04/02/2021 issued by Jiangsu food and drug administration. **Aminophylline:**

		M/s Hebei Guangxiang Pharamceutical Co., Ltd., east of Jingliu road, Lingang Chemical Industrial Park, Cangzhou City, Hebei province, China. GMP certificate no. HE20190094 valid till 02/09/2024 issued by Hebei Drug Administration. **Ammonium Chloride:** M/s Rasino Herbs pvt., Ltd., N-2, MIDC Kupwad, SAngli 416436, Tal-Miraj % Dist Sangli, Maharashtra, India. GMP certificate No. 6098069 valid till 08/02/2022 issued by Food and Drugs Administration Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	**Aminophylline:** • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (031908001, 031908002, 031908003) **Diphenhydramine HCl:** • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DH_201701501, DH-201701502, DH-201701503) **Ammonium chloride:** • Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Batches: (NH/6232-13, NH/6307-13, NH/6380-13) • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (NH794017, NH794117, NHP18004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted pharmaceutical equivalence studies against: Brand: Hydyllin Syrup 120mL Mfg by M/s Searle Batch: AW061 By performing quality tests.
	Analytical method validation/verification of product	Method validation / verification studies have submitted including accuracy/recovery, precision, specificity, , system suitability etc for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	**Diphenhydramine HCl:** M/s Qidong Dongyue Pharmaceutical Co., Ltd., No. 268 Shanghai road, Binjiang fine chemical industry zone, Qidong City, Jiangsu province, China. GMP certificate no. JS20160535 valid till 04/02/2021 issued by Jiangsu food and drug administration. **Aminophylline:** M/s Hebei Guangxiang Pharamceutical Co., Ltd., east of Jingliu road, Lingang Chemical Industrial Park, Cangzhou City, Hebei province, China. GMP certificate no. HE20190094 valid till 02/09/2024 issued by Hebei Drug Administration. **Ammonium Chloride:** M/s Rasino Herbs pvt., Ltd., N-2, MIDC Kupwad, SAngli 416436, Tal-Miraj % Dist Sangli, Maharashtra, India. GMP certificate No. 6098069 valid till 08/02/2022 issued by Food and Drugs Administration Maharashtra State, India.		
API Lot No.	Aminophylline: 032011037 Diphenhydramine: Ammonium chloride: NHP21033		
Description of Pack (Container closure system)	Ambe colured glass bottle sealed with aluminium cap.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-004	Trial-004	Trial-004
Batch Size	80 bottles	80 bottles	80 bottles
Manufacturing Date	22/11/2021	25/11/2021	27/11/2021
Date of Initiation	30/11/2021	30/11/2021	30/11/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Diphenhydramine HCl:** GMP certificate no. JS20160535 valid till 04/02/2021 issued by Jiangsu food and drug administration. **Aminophylline:** GMP certificate no. HE20190094 valid till 02/09/2024 issued by Hebei Drug Administration. **Ammonium Chloride:** GMP certificate No. 6098069 valid till 08/02/2022 issued by Food and Drugs Administration Maharashtra State, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice number HBGL-2012031429 dated 03/12/2020 cleared on 18/12/2020 vide diary number 18587/2020DRAP for Aminophylline Anhydrous. Copy of invoice number E013/21-22 dated 25/04/2021 cleared on 05/05/2021 vide diary number 6809/2021DRAP dated 05/05/2021 for Ammonium Chloride. Copy of invoice number 21A-010 dated 02/02/2021 cleared on 11/02/2021 vide diary number 2287/2021-DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**N/A**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Sr. No.	Observations	Response
1	Provide COA of Diphenhydramine HCl drug substance for the batch which has been used for product development from drug product manufacturer.	The firm has submitted COA of Batch Number: DH-202101203 of Diphenhydramine HCl from drug substance and drug product manufacturer.
2	Provide analytical method verification studies (including accuracy, specificity and precision) for drug substance performed by drug product manufacturer of Diphenhydramine HCL drug substance performed by drug product manufacturer.	Submitted.
3	Provide pharmaceutical equivalence studies against innovator's / reference product by performing all the quality tests.	The firm has submitted pharmaceutical equivalence studies against:

		Brand: Hydyllin Syrup 120mL Mfg by M/s Searle Batch: AW061 By performing quality tests.
4	Provide complete batch manufacturing record along with the detail of quantity dispensed for manufacturing.	The firm has submitted complete batch manufacturing record for the applied product.
5	Provide documents for the procurement of API with approval from DRAP (in case of import) for all the three drug substances.	Copy of invoice number HBGL-2012031429 dated 03/12/2020 cleared on 18/12/2020 vide diary number 18587/2020DRAP for Aminophylline Anhydrous. Copy of invoice number E013/21-22 dated 25/04/2021 cleared on 05/05/2021 vide diary number 6809/2021DRAP dated 05/05/2021 for Ammonium Chloride. Copy of invoice number 21A-010 dated 02/02/2021 cleared on 11/02/2021 vide diary number 2287/2021-DRAP.
6	Please provide compatibility studies of excipients with drug substance.	Compatibility studies of excipients with the drug substances have been submitted.
7	Provide evidence of approval of the applied product in reference regulatory authorities as provided in 275th meeting of Registration Board.	Could not be confirmed
8	Justification is required since the trial batches have been manufactured before the grant of "Oral Liquid Section (General)'.	*Please be informed that all trial batches are developed in R&D lab.*

Decision: Deferred for evidence of approval of the applied formulation in reference regulatory authorities which were declared/approved by the Registration Board in its 275th meeting.

1451.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Name, address of Manufacturing site.	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26230 dated 16/09/2022
	Details of fee submitted	PKR 30,000/-: dated 05/04/2022
	The proposed proprietary name / brand name	**Ketis Syrup 1mg/5mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Ketotifen as Hydrogen Fumarate……..1mg
	Pharmaceutical form of applied drug	Clear colorless solution with apricot flavor

	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	1's (60mL)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zaditen Oral Solution 1mg/5mL, HPRA Ireland Approved.
	For generic drugs (me-too status)	Zatofen Syrup 1mg/5mL by Novartis Phram.
	GMP status of the Finished product manufacturer	Inspection report dated 03/01/2022 & 04/01/2022 is submitted. The panel recommended renewal of DML.
	Section approval	Oral Liquid Section (General) vide letter no.F.1-1/86-Lic(Vol-V) dated 7th June, 2022.
	Name and address of API manufacturer.	M/s Suzhou Homesun Pharmaceutical Co., Ltd., No. 12 West Xiexin road, Taicang Port Development Zone, Taicang City, Jiangsu Province China. Copy of GMP certificate no. JS20170699 valid till 03/09/2022 issued by Jiangsu Food and Drug Administration.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	• Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months (KETIII/00319 (24 months, KETIII/00420 (12 months, KETIII/00520, KETIII/00620) • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (KETIII/00718, KETIII/00818, KETIII/00918)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted pharmaceutical equivalence against Zatofen Syrup 60mL Mfg by M/s Novarits by performing quality tests. Batch number: JLRAAH
	Analytical method validation/verification of product	Method validation / verification studies have submitted including accuracy/recovery, precision, specificity, , system suitability etc for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Suzhou Homesun Pharmaceutical Co., Ltd., No. 12 West Xiexin road, Taicang Port Development Zone, Taicang City, Jiangsu Province China.		
API Lot No.	20201005		
Description of Pack (Container closure system)	Amber colored glass bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	50bottles	50bottles	50bottles
Manufacturing Date	18/02/2021	18/02/2021	18/02/2021
Date of Initiation	18/02/2021	18/02/2021	18/02/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. JS20170699 valid till 03/09/2022 issued by Jiangsu Food and Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice number 01005SLT2012401-2 dated 08/01/2021 cleared vide diary number 1439/2021-DRAP dated 26/01/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**N/A**
6.	Record of Digital data logger for temperature and humidity monitoring	Submitted

	of stability chambers (real time and accelerated)	

Remarks OF Evaluator-I:

Sr. No.	Observations	Response
1	As per Section 1.6.5 the drug substance manufacturer is M/s Suzhou Homesun Pharmaceutical Co., Ltd., while as per Module II and III and as per the submitted documents the manufacturer is M/s Fleming Laboratories Limited, India, Please clarify. Moreover, provide GMP certificate of drug substance manufacturer along with the correct name and address of drug substance manufacturer in-lined with the name and address mentioned in GMP certificate.	The manufacturer of API is M/s Suzhou Homesun Pharmaceutical Co., Ltd., No. 12 West Xiexin road, Taicang Port Development Zone, Taicang City, Jiangsu Province China. The firm has provided relevant documents including GMP certificate. Stability study of API is submitted already with the initial application. Copy of GMP certificate no. JS20170699 valid till 03/09/2022 issued by Jiangsu Food and Drug Administration
2	Please provide detail of specifications of the drug substance along with the submission of detail of analytical procedures.	Submitted.
3	Please provide detail of reference standard along with the COAs in relevant section since the information is not provide din the submitted dossier.	Submitted. Batch number: 20201105
4	Provide analytical method verification studies including accuracy, specificity and precision for drug substance performed by drug product manufacturer.	The firm has submitted analytical method verification studies including specificity, accuracy and precision from drug product manufacturer long with the protocol.
5	Detail of container closure system for the drug substance.	Submitted.
5	Provide Pharmaceutical Equivalence studies against reference / innovator's product by performing all the quality tests.	The firm has submitted pharmaceutical equivalence against Zatofen Syrup 60mL Mfg by M/s Novarits by performing quality tests. Batch number: JLRAAH
6	Provide COA of relevant batch used for the product development of the applied product from drug substance as well as from the drug product manufacturer.	COA is submitted from drug product manufacturer and drug substance manufacturer. Batch number: 20201005
7	The excipients used in the applied formulation are different from the excipients used by the innovator, therefore, you are required to submit compatibility studies of excipients with the drug substance.	Drug-excipient compatibility studies have been submitted.
8	UV method has been developed for analysis of the drug product instead of HPLC method, please justify.	*The product is developed according to In-House specifications. At the time of product development phase, we have developed the analytical method of Ketis Syrup on UV spectrophotometer for performance of assay test along with the performance of analytical method validation studies.*
9	Please provide detail of reference standard along with the relevant COAs.	Submitted.

10	Stability summary sheets for batch number T002 for 3rd month time point of accelerated stability studies are not provided.	The firm has submitted stability summary sheets for batch number T002 for 3rd month time point of accelerated stability studies.
11	Provide documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice number 01005SLT2012401-2 dated 08/01/2021 cleared vide diary number 1439/2021-DRAP dated 26/01/2021.
12	Provide complete batch manufacturing record.	Submitted.
13	Justification is required since the trial batches have been manufactured before the grant of "Oral Liquid Section (General)'.	*Please be informed that all trial batches are developed in R&D lab.*

Decision: Registration Board deferred the case for submission of complete testing including Assay test using HPLC method on the next time point of long term stability studies along with analytical method validation studies.

1452.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Name, address of Manufacturing site.	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27906 dated 03/10/2022
	Details of fee submitted	PKR 30,000/-: dated 05/04/2022
	The proposed proprietary name / brand name	PD-Ron Syrup 50mg/5mL
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Iron as Iron (III) Hydroxide Polymaltose Complex……50mg
	Pharmaceutical form of applied drug	Dark brown slightly viscous but clear uniform solution (chocolate flavour)
	Pharmacotherapeutic Group of (API)	Anti-anemic
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	1's (120mL)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	
	For generic drugs (me-too status)	Rubifer Syrup by M/s AGP, Reg. No. 028123
	GMP status of the Finished product manufacturer	Inspection report dated 03/01/2022 & 04/01/2022 is submitted. The panel recommended renewal of DML.
	Section approval	Oral Liquid Section (General) vide letter no.F.1-1/86-Lic(Vol-V) dated 7th June, 2022.

	Name and address of API manufacturer.	M/s Chemiworld Private Limited, plot no. 97, J-Industrial Estate Jamrud, Peshawar.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	• Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (F06-IPC-211, G06-IPC-221, G06-IPC-223)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalene studies have been submitted against Rubifer Syrup 120mL mfg by M/s AGP. Batch number: B5032
	Analytical method validation/verification of product	Method validation / verification studies have submitted including accuracy/recovery, precision, specificity, , system suitability etc for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Chemiworld Private Limited, plot no. 97, J-Industrial Estate Jamrud, Peshawar.
API Lot No.	F21-IPC-530
Description of Pack (Container closure system)	Amber colored glass bottle
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	TT-003	TT-004	TT-005
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	02/07/2021	02/07/2021	02/07/2021
Date of Initiation	10/07/2021	10/07/2021	10/07/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML no. 000579 issued on 19/07/2017 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Locally purchased.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**N/A**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Sr. No.	Observations	Response
1	Provide GMP certificate of drug substance manufacturer.	Copy of GMP certificate no. F.3-20/2017-DRAP-90 issued on the basis of inspection conducted on 29/11/2016. Copy of DML issued on 19/07/2017 is submitted.
2	Justification is required regarding the selection of titration method for estimation of elemental Iron in the applied formulation, please.	*The applied product is non-pharmacopoeial and the analytical method used for analysis is in-house and validated. Validation studies have been submitted.*
3	Provide analytical method verification studies including accuracy, specificity and precision for drug substance performed by drug product manufacturer.	Submitted. Results of Accuracy, precision and specificity are submitted.
4	Provide COAs of the batch of drug substance which has been used for product development from drug product manufacturer as well as from drug substance manufacturer.	COAs of relevant batch from drug product manufacturer and drug substance manufacturer are submitted. Batch number: F21-IPC-530
5	Detail of container closure system for the drug substance.	Submitted,

6	Provide Pharmaceutical Equivalence studies against reference / innovator's product by performing all the quality tests.	Pharmaceutical equivalene studies have been submitted against Rubifer Syrup 120mL mfg by M/s AGP. Batch number: B5032
7	Provide COA of relevant batch used for the product development of the applied product from drug substance as well as from the drug product manufacturer.	COAs of relevant batch from drug product manufacturer and drug substance manufacturer are submitted. Batch number: F21-IPC-530
8	Compatibility studies of excipients with drug substance is required.	Submitted,
9	Detail of analytical method for finished product is required.	Submitted.
10	Justification is required since the trial batches have been manufactured before the grant of "Oral Liquid Section (General)'.	*Please be informed that all trial batches are developed in R&D lab.*
11	Provide stability study data for drug substance (including accelerated and real time stability) conducted under the conditions of Zone IV-A.	• Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (F06-IPC-211, G06-IPC-221, G06-IPC-223)

Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of fee Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.

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

Routine application submitted on form 5 (Local manufacturing):

1453.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals (PVT) Ltd, plot no.9-B 1&2, old industrial estate, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	DAMBOX 10mg tablets
	Diary No. Date of R& I & fee	Dy.No. 35580 dated 26/10/2018 PKR 20,000/-
	Composition	Each Film Coated Tablet contains: Bambuterol ……10mg
	Pharmacological Group	Beta adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	MFg specs
	Pack Size & Demanded Price	1×10's & 1×30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Bambec tablets 10mg of M/s AstraZeneca UK Limited (MHRA Approved)
	Me-too Status	Pulmitac 10mg tablet of M/s Platinum Pharmaceuticals (Reg.# 026684)
	GMP Status	**LAST INSPECTION REPORT DATED 16/06/2017 AND 25/07/2017, THE PANEL RECOMMENDED THE RENEWAL OF LICENSE BY THE WAY OF FORMULATION.**
	Remarks of the Evaluator-I:	
	The composition of the applied formulation is not according to the reference product. The reference product contains Bambuterol	The firm has revised master formulation from "each film coated tablet contains Bambuterol 10mg" to "each tablet contains Bambuterol HCl 10mg" as per the innovator's product.

	Hydrochloride while the applied product contains Bambuterol. Moreover, the reference product is uncoated while the applied product is film coated. Clarification is required or otherwise the formulation should be revised along with the submission of requisite fee.	The firm has submitted Rs. 30,000/- fee for revision of formulation vide challan number 123973765306 dated 22/08/2022. Each Tablet contains: Bambuterol hydrochloride……10mg
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of latest GMP inspection report valid within the last three years.	
1454.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals (PVT) Ltd, plot no.9-B 1&2, old industrial estate, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	DAMBOX 20mg tablets
	Diary No. Date of R& I & fee	Dy.No. 35581 dated 26/10/2018 PKR 20,000/-
	Composition	Each Film Coated Tablet contains: Bambuterol……20mg
	Pharmacological Group	Beta adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	MFg specs
	Pack Size & Demanded Price	1×10's & 1×30's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Bambec tablets 20mg of M/s AstraZeneca UK Limited (MHRA Approved)
	Me-too Status	Bastrol 20mg tablet by M/s Bosch, Reg No. 55542
	GMP Status	**LAST INSPECTION REPORT DATED 16/06/2017 AND 25/07/2017, THE PANEL RECOMMENDED THE RENEWAL OF LICENSE BY THE WAY OF FORMULATION.**
	Remarks of the Evaluator-I:	
	The composition of the applied formulation is not according to the reference product. The reference product contains Bambuterol Hydrochloride while the applied product contains Bambuterol. Moreover, the reference product is uncoated while the applied product is film coated. Clarification is required or otherwise the formulation should be revised along with the submission of requisite fee.	The firm has revised master formulation from "each film coated tablet contains Bambuterol 10mg" to "each tablet contains Bambuterol HCl 10mg" as per the innovator's product. The firm has submitted Rs. 30,000/- fee for revision of formulation vide challan number 77649461725 dated 22/08/2022. Each Tablet contains: Bambuterol hydrochloride……20mg
	Decision: Approved with innovator's specifications. Registration letter will be issued after submission of latest GMP inspection report valid within the last three years.	
1455.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals (PVT) Ltd, plot no.9-B 1&2, old industrial estate, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	DEULUX 30mg capsule
	Diary No. Date of R& I & fee	Dy.No. 35585 dated 26/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Duloxetine as enteric coated pellets……30mg
	Pharmacological Group	Beta adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cymbalta (Duloxetine 30 mg capsule) by M/s Eli Lilly, USFDA
	Me-too Status	Dulan (Duloxetine 30 mg capsule) by M/s Hilton Pharma. (Reg#055447)
	GMP Status	**LAST INSPECTION REPORT DATED 16/06/2017 AND 25/07/2017, THE PANEL RECOMMENDED THE RENEWAL OF LICENSE BY THE WAY OF FORMULATION.**
	Remarks of the Evaluator-I:	
	Provide source of pellets, GMP certificate of manufacturer of pellets , stability studies according to Zone IV-A and if the pellets are imported then submit the differential fee as well.	Source of Pellets: M/s Vision Pharma Firm has submitted copy of GMP certificate dated 31-07-2019 issued by Additional Director (QA&LT) DRAP Islamabad. The certificate is valid till 10-02-2022. Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	The product in reference country is approved as Duloxetine as Hydrochloride enteric coated pellets while the applied product contains Duloxetine enteric coated pellets, clarify or otherwise revise the formulation along with the submission of requisite fee.	The firm has stated that due to typographical error Hydrochloride was not mentioned. The firm has revised the formulation. The firm has submitted Rs. 30,000/- fee for pre-registration variation fee vide challan number 871913625322 dated 22/08/2022. Each capsule contains: Duloxetine as hydrochloride (enteric coated pellets) …….20mg
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report valid within the last three years.	
1456.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals (PVT) Ltd, plot no.9-B 1&2, old industrial estate, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	DEULUX 20mg capsule
	Diary No. Date of R& I & fee	Dy.No. 35584 dated 26/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Duloxetine as enteric coated pellets……20mg
	Pharmacological Group	Beta adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cymbalta (Duloxetine 20 mg capsule) by M/s Eli Lilly, USFDA Approved
	Me-too Status	Dulan (Duloxetine 20 mg capsule) by M/s Hilton Pharma. (Reg#055446)
	GMP Status	**LAST INSPECTION REPORT DATED 16/06/2017 AND 25/07/2017, THE PANEL RECOMMENDED THE RENEWAL OF LICENSE BY THE WAY OF FORMULATION.**
	Remarks of the Evaluator-I:	
	Provide source of pellets, GMP certificate of manufacturer of pellets ,	Source of Pellets: M/s Vision Pharma

	stability studies according to Zone IV-A and if the pellets are imported then submit the differential fee as well.	Firm has submitted copy of GMP certificate dated 31-07-2019 issued by Additional Director (QA&LT) DRAP Islamabad. The certificate is valid till 10-02-2022. Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	The product in reference country is approved as Duloxetine as Hydrochloride enteric coated pellets while the applied product contains Duloxetine enteric coated pellets, clarify or otherwise revise the formulation along with the submission of requisite fee.	The firm has stated that due to typographical error Hydrochloride was not mentioned. The firm has revised the formulation. The firm has submitted Rs. 30,000/- fee for pre-registration variation fee vide challan number 990820791440 dated 22/08/2022. Each capsule contains: Duloxetine as hydrochloride (enteric coated pellets) …….20mg
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report valid within the last three years.	
1457.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals (PVT) Ltd, plot no.9-B 1&2, old industrial estate, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	DEULUX 60mg capsule
	Diary No. Date of R& I & fee	Dy.No. 35586 dated 26/10/2018 PKR 20,000/-
	Composition	Each capsule contains: Duloxetine as enteric coated pellets……60mg
	Pharmacological Group	Beta adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Cymbalta (Duloxetine 60 mg capsule) by M/s Eli Lilly, USFDA Approved
	Me-too Status	Dulan (Duloxetine 60 mg capsule) by M/s Hilton Pharma. (Reg#055448)
	GMP Status	**LAST INSPECTION REPORT DATED 16/06/2017 AND 25/07/2017, THE PANEL RECOMMENDED THE RENEWAL OF LICENSE BY THE WAY OF FORMULATION.**
	Remarks of the Evaluator-I:	
	Provide source of pellets, GMP certificate of manufacturer of pellets , stability studies according to Zone IV-A and if the pellets are imported then submit the differential fee as well.	Source of Pellets: M/s Vision Pharma Firm has submitted copy of GMP certificate dated 31-07-2019 issued by Additional Director (QA&LT) DRAP Islamabad. The certificate is valid till 10-02-2022. Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	The product in reference country is approved as Duloxetine as	The firm has stated that due to typographical error Hydrochloride was not mentioned. The firm has

	Hydrochloride enteric coated pellets while the applied product contains Duloxetine enteric coated pellets, clarify or otherwise revise the formulation along with the submission of requisite fee.	revised the formulation. The firm has submitted Rs. 30,000/- fee for pre-registration variation fee vide challan number 2016436254 dated 22/08/2022. Each capsule contains: Duloxetine as hydrochloride (enteric coated pellets) …….60mg
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report valid within the last three years.	
1458.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals (PVT) Ltd, plot no.9-B 1&2, old industrial estate, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	ZELUCAST 20mg tablets
	Diary No. Date of R& I & fee	Dy.No. 35583 dated 26/10/2018 PKR 20,000/-
	Composition	Each Film coated tablet contains: Zafirlukast……20mg
	Pharmacological Group	Beta adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	1×14's & 1×28's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Accolate 20mg film-coated tablets of M/s Astra Zeneca Pharmaceuticals (USFDA Approved)
	Me-too Status	Zilesta 20mg tablet of M/s Genix Pharma, Reg No. 55979
	GMP Status	**LAST INSPECTION REPORT DATED 16/06/2017 AND 25/07/2017, THE PANEL RECOMMENDED THE RENEWAL OF LICENSE BY THE WAY OF FORMULATION.**
	Remarks of the Evaluator-I:	
	Provide master formulation.	Submitted.
	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of fee Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021 and submission of latest GMP inspection report valid within the last three years.	
1459.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals (PVT) Ltd, plot no.9-B 1&2, old industrial estate, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	ZELUCAST 10mg tablets
	Diary No. Date of R& I & fee	Dy.No. 35582 dated 26/10/2018 PKR 20,000/-
	Composition	Each Film coated tablet contains: Zafirlukast……10mg
	Pharmacological Group	Beta adrenoceptor agonist
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	1×14's, Price as per SRO
	Approval Status of Product in Reference Regulatory Authorities	Accolate 10mg film-coated tablets of M/s Astra Zeneca Pharmaceuticals (USFDA Approved)
	Me-too Status	Zilesta 10mg tablet of M/s Genix Pharma, Reg No. 55978
	GMP Status	**LAST INSPECTION REPORT DATED 16/06/2017 AND 25/07/2017, THE PANEL RECOMMENDED THE RENEWAL OF LICENSE BY THE WAY OF FORMULATION.**
	Remarks of the Evaluator-I:	
	Provide master formulation.	Submitted.

	Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of fee Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021 and submission of latest GMP inspection report valid within the last three years.

Deferred cases submitted on Form 5 (Local manufacturing):

Sr. No.	Name of manufacturer	Brand name / composition / Pharmacological group / specifications	Type of Form / Dy. No. / Fee / Pack size / Proposed price	RRA reference / me-too / Latest GMP inspection report	Remarks
1460.	Moon Pharmaceuticals Plot No. 5,SS-4 Road, National Industrial Zone, Rawat, Islamabad	Capsule Monzit 500mg Capsule Each capsule contains: Azithromycin (as Dihydrate) .500mg Macrolide Antibiotic (USP Specification) USP35–NF30 Page 2283	Form 5 17-10-2016 Dy.No.1681 Rs.20,000/= 1x 5's As Per SRO	Azithromax by Pfizer pharma, Azilite By Webros pharma Inspection report dated 29-12-2015 showing compliance of GMP as Good and recommended the grant of DML	SRA status could not be confirmed
	Decision of 265th meeting: Deferred for confirmation from Registration section about already approved products against this section **Submission by the firm:** The firm has stated that the RRAs reference for the applied product is not available. The firm has requested for change of dosage form of the applied product from 500mg Capsule to 500mg Film coated Tablet. The firm has submitted revised for 5 along with the annexures. **Brand name:** Monzit 500mg tablet Each film coated tablet contains: USP specifications Pack size and price: As per SRO **GMP inspection report:** Firm has submitted inspection report dated 11/12/2019 conducted to verify rectification status of observations noted in previous inspection. The panel in its written statement on inspection book mentioned that the firm is operating at acceptable level of GMP as of today. The panel in its detailed report concluded that firm has rectified majority of observation sand the report is being forwarded to competent authority for resumption of production activities in oral liquid syrup section.				
	Decision: Approved. Registration letter will be issued after submission of latest GMP inspection report conducted within last three years along with evidence of availability of HPLC equipped with Amperometric electrochemical detector.				

1461.	**Name and address of manufacturer / Applicant**	**M/s Rotex Pharma Pvt Ltd., Plot No. 206 & 207. industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Primus 5mg dispersible tablet
	Diary No. Date of R& I & fee	Dy.No. 5600 dated: 07/02/2019 Rs.20,000/-
	Composition	Each dispersible tablet contains: Everolimus….5mg
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	From 5
	Finished Product Specification	Manufacturer's specs
	Pack Size & Demanded Price	10's, 30's, 50's, 60's, 90's, As per SRO
	Approval Status of Product in Reference Regulatory Authorities	AFINITOR DISPERZ TABLET FOR ORAL SUSPENSION. USFDA Approved
	Me-too Status	Could not be confirmed

	GMP Status	Following additional sections were approved vide letter No.F.1-53/2003-Lic.(Vol-I) dated 13th June, 2017. • Tablet (oncology) • Capsule (oncology) • Liquid vial SVP (oncology) • Liquid Ampoule SVP (Onclology) • Dry powder vial (oncology) • Capsule (Ceph) • Dry [powder for oral suspension (ceph) • Dry Powder vial (ceph) • Dry Powder vial (Ceph)
	Remarks of the Evaluator.	
	Decision: Decision of 278rd meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm and confirmation of pharmacological group **Submission by the firm:** • Copy of GMP certificate No. F.3-55/2020-Addl.Dir.(QA&LT-1) issued on the basis of inspection conducted on12/08/2020. • **Me-too:** Afinitor 5Mg Dispersible Tablets by M/s Novartis Pharma (Pakistan) Limited, Reg. no. 088398. (Approved in 263rd meeting) • **Pharmacological group:** Immunosuppressant / Protein Kinase Inhibitor **2.7 Administration and Preparation of AFINITOR DISPERZ in SEGA with TSC** Do not combine the two dosage forms (AFINITOR Tablets and AFINITOR DISPERZ) to achieve the desired dose. Use one dosage form or the other. Administer AFINITOR DISPERZ (everolimus tablets for oral suspension) as a suspension only. Administer AFINITOR DISPERZ orally once daily at the same time every day. Administer either consistently with food or consistently without food *[see Clinical Pharmacology (12.3)]*. Administer suspension immediately after preparation. Discard suspension if not administered within 60 minutes after preparation. Prepare suspension in water only.	
	Decision: Registration Board deferred the case for submission of stability studies data as per checklist of 293rd meeting of DRB, in light of the Notification No. 320-DRB/ 2022(PE&R) dated 17th October 2022.	

1462.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd., Plot No. 206 & 207. industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Texflu 250mg Tablet
	Diary No. Date of R& I & fee	Diary No:8171, 10-07-2017, Rs: 20,000/-
	Composition	Each tablet contains: Flutamide …250mg
	Pharmacological Group	Anti-Androgen
	Type of Form	From 5
	Finished Product Specification	Manufacturer's specs
	Pack Size & Demanded Price	60's, 100's/ As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Flutamide 250 mg Tablets by M/s Sovereign Medical (MHRA Approved)
	Me-too Status	Eulexin Tablets 250mg by M/s Atco (Reg#014625)
	GMP Status	Following additional sections were approved vide letter No.F.1-53/2003-Lic.(Vol-I) dated 13th June, 2017. • Tablet (oncology)

		• Capsule (oncology) • Liquid vial SVP (oncology) • Liquid Ampoule SVP (Onclology) • Dry powder vial (oncology) • Capsule (Ceph) • Dry [powder for oral suspension (ceph) • Dry Powder vial (ceph) • Dry Powder vial (Ceph)
	Remarks of the Evaluator.	
	Decision: Decision of 282nd meeting: Deferred for further discussion regarding required manufacturing facility. **Submission by the firm:** • Copy of GMP certificate No. F.3-55/2020-Addl.Dir.(QA&LT-1) issued on the basis of inspection conducted on12/08/2020. • The firm has stated that the ATC code for Flutamide is L02 (Anti-Androgen). https://www.whocc.no/atc_ddd_index/?code=L02BB01 **(**WHO ATC Code) • The innovator's product is Dispersible tablet for Oral Suspension.	
	Decision: Registration Board approved registration of product with innovator's specifcations in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. • **Registration Board further decided that registration letter will be issued after submission of fee Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**	

Miscellaneous Cases:

1463.	Name, address of Applicant / Marketing Authorization Holder	M/s Cunningham Pharmaceuticals (Pvt.) Ltd. Plot No. 81, Sunder industrial Estate Raiwind Road, Lahore, Pakistan
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt.) Ltd. Plot No. 81, Sunder industrial Estate Raiwind Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33172 Dated 21-12-2021
	Details of fee submitted	PKR 20,000/-: Dated 11-03-2020
	The proposed proprietary name / brand name	NU-ORS Sachet (Orange Flavor)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet Contains: Sodium chloride……...2.60gm Potassium chloride……..….1.50gm Tri-sodium citrate dihydrate…....2.90gm Dextrose anhydrous……..13.50gm
	Pharmaceutical form of applied drug	Granule to be reconstituted for oral administration

	Pharmacotherapeutic Group of (API)	Oral Rehydration Salts
	Reference to Finished product specifications	BP specifications
	Proposed Pack size	1 x 20's Sachets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	WHO Approved.
	For generic drugs (me-too status)	OEM Orange Flavour, Indus Pharma Karachi (Reg # 067312)
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 01-04-2019. The firm has provided sachet section.
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Dominion salt Ltd., Totara street, Mount Maunganui, New Zealand. **Potassium Chloride:** M/s K+S KALI GmbH Germany, Am Kaliwerk 6, 36119 Neuhof, Germany **Trisodium Citrate:** M/s. Weifang Ensign Industry Co., Ltd. No. 1567, Changsheng Street, Changle, Weifang, shandong province, China. **Dextrose Anhydrous:** M/s Xiwang pharmaceutical., No. 237, Tongfu Road, Handian Town, Zouping Country, Binzhou city, Shandong Province, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance is submitted. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	Official monograph of oral rehydration salts is present in BP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substances.
	Stability studies	**Sodium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. **Potassium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months. **Trisodium citrate dihydrate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months. **Glucose anhydrous:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III (Drug Product):	The firm has submitted details of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence has been established against the comparator product OEM (ORS) orange flavour (Batch # OR-4043) by M/s Indus Pharma, Karachi by performing quality tests (Description, LOD, Average weight and Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision and specificity.
STABILITY STUDY DATA		
Manufacturer of API	**Sodium Chloride:** M/s Dominion salt Ltd., Totara street, Mount Maunganui, New Zealand. **Potassium Chloride:**	

	M/s K+S KALI GmbH Germany, Am Kaliwerk 6, 36119 Neuhof, Germany **Tri Sodium Citrate:** M/s. Weifang Ensign Industry Co., Ltd. No. 1567, Changsheng Street, Changle, Weifang, shandong province, China. **Dextrose Anhydrous:** M/s Xiwang pharmaceutical., No. 237, Tongfu Road, Handian Town, Zouping Country, Binzhou city, Shandong Province, P.R. China.		
API Lot No.	Sodium Chloride: 24042018 Potassium Chloride: 711800743 Trisodium Citrate: ST1803283 Glucose Anhydrous (Dextrose): 211901315		
Description of Pack (Container closure system)	Aluminium Foil Sachets packed in unit carton (1×20's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	OT001	OT002	OT003
Batch Size	200 Sachet	200 Sachet	200 Sachet
Manufacturing Date	10-2019	10-2019	11-2019
Date of Initiation	07-10-2019	09-10-2019	07-11-2019
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** The firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt Limited, New Zealand issued by Ministry of health, New Zealand. The certificate is valid till 29-07-2021. **Potassium Chloride:** The firm has submitted copy of GMP certificate of M/s K+S Kali GmbH issued by Regierungsprasidium, Darmstadt Germany. The certificate is valid till 06-03-2021. **Tri Sodium Citrate:** The firm has submitted document of verification of compliance certificate of M/s Weifang Ensign Industry Co., Ltd., China issued by SGS-CSTC Standards Technical services Co. ltd. The certificate is valid till 28-06-2024. **Dextrose Anhydrous:** Firm has submitted copy of GMP certificate (No. SD2020170644) of M/s Xiwang Pharmaceutical Co., ltd. China issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium chloride dated 17-09-2019. **Potassium Chloride:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of potassium chloride dated 17-09-2019. **Tri Sodium Citrate:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium citrate dated 17-09-2019. **Dextrose Anhydrous:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of Dextrose anhydrous dated 17-09-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.	The firm has submitted data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not applicable.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	The firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

Sr. No.	**Observations**	**Response by the Firm**
1.	Copy of GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	The firm has submitted request for renewal of GMP certificate to Director General (E & M), Lahore.
2.	Submit data of verification of analytical procedure of each drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted."*	The firm has submitted analytical method verification studies for each drug substance.
3.	Submit evidence of availability of atomic emission spectroscopy / flame photometer which is required in the testing of the drug product as per BP monograph.	The firm has submitted copy of invoice for the purchase of Flame photometer (Model: PFP7) from Western Analytical services dated 06-11-2019 (Invoice # 01119/097).
4.	Submit evidence of purchase / import documents of each drug substance.	**Sodium Chloride:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium chloride dated 17-09-2019. **Potassium Chloride:**

		Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of potassium chloride dated 17-09-2019. **Tri Sodium Citrate:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of sodium citrate dated 17-09-2019. **Dextrose Anhydrous:** Firm has submitted copy of invoice from Mak Kemikal, Karachi specifying purchase of 25Kg of Dextrose anhydrous dated 17-09-2019.

Decision of 321st meeting: Registration Board referred the case to QA & LT division seeking opinion regarding use of API imported by the indenter not having valid DML.

Evaluation by PEC:

The case was forwarded to QA & LT division through file number 7-1/2019-PEC dated 18/11/2022. QA&LT division has opined that;

"As per Drugs (Import & Export) Rules, 1976 ad Drugs (LR&A) Rules, 1976 only Licensed Manufacturer can import the API for manufacture of registered products or products for the purpose of test or analysis etc. In the light of above it is submitted that purchase of API from and indenter not having DML is not legitimate".

Submission by the firm:

The firm has stated that:

- It is to be informed that we had purchased all of API's for our product ORS from an authorized vendor/indenter and all of these had been purchased by our vendor from licensed manufacturers as GD's attached.
- All of the API's used in ORS i-e. Dextrose, Sodium Chloride, Potassium Chloride, Tri-Sodium Citrate are also used as excipients that's why we had purchased all these from authorized vendor.
- All of the API's used in ORS are Pharmaceutical Grade
- The firm has submitted GDs
- Relevant certificate of Analysis from the drug substance manufacturers have been submitted.

Decision: Registration Board after thorough discussion regarding the purchase of drug substances from an unauthorized intender not having Drug Manufacturing License and considering the opinion from QA & LT Division, decided to reject the application.

Applications for Withdrawal:

1464. M/s May & Baker (PVT) Ltd.45km, Dina Nath, Multan road Lahore.

Product:
Ketaro 100mg/2mL Ampoule
Each mL contains:
Ketamine as Hydrochloride…….50mg

Dy. No.: 26381 dated 19/09/2022

Submission by the firm:

The firm has stated vide their letter dated 24/10/2022 that they had decided to develop the product using new source of drug substance therefore we want to withdraw the application for registration of the product Ketaro 100mg/2mL Ampoule.

Decision: Registration Board acceded to request of the applicant and rejected the case.

1465. M/s Bio Labs Pvt. Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad has applied for registration of the following products in new section / new license:

A. Orizec 40mg Injection

Each Vial Contains:
Omeprazole Sodium Eq. to Omeprazole…40mg
Type of form: Form-5F
Dy.No 8917 dated 07-04-2022
Rs.30,000/- dated 03-02-2022

B. Esozek 40mg Injection

Each Vial Contains:
Esomeprazole Sodium Eq. to Esomeprazole…40mg
Type of form: Form-5F
Dy.No 11099 dated 07-05-2022
Rs.75,000/- dated 03-02-2022

C. Pantozek 40mg Injection

Each Vial Contains:
Pantoprazole Sodium Eq. to Pantoprazole…40mg
Type of for: Form-5F
Dy.No 19956 dated 07-07-2022
Rs.30,000/- dated 03-02-2022

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

1. B-Cap 40mg
Each vial contains:
Omeprazole (as Sodium)……..40mg
Lyophilized Powder
Registration number: 075061

2. E-Zole 40mg
Each vial contains:
Esomeprazole (as Sodium)…….40mg
Lyophilized Powder
Registration number: 075062

3. Pancap 40mg
Each vial contains:
Pantoprazole (as Sodium)…….40mg
Lyophilized Powder
Registration number: 075060

*The registrations of the above mentioned products were granted vide letter No.F.8-6/2012Reg.III(M-236) dated 19th December, 2012.

The case is hereby placed before the Board.

Decision: Registration Board was apprised that the applicant already hold registration of the above mentioned finished products manufactured by way of lyophilisation which is being carried out in lyophilisation section. The Board discussed that the new applied products contain same formulation as that of already registered products thus the Board decided to reject the applications for Orizec 40mg Injection, Esozek 40mg Injection and Pantozek 40mg Injection.

Agenda of Evaluator PEC-II:

Case no. 01 New Registration applications on Form 5F (Human)

a. New Cases (Human)

1466.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry vial section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31772 dated 18-11-2021
	Details of fee submitted	Rs.75,000/- dated 21-10-2021
	The proposed proprietary name / brand name	**Colist 1 MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Colistimethate sodium……1 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials with grey rubber stopper with an aluminium cap
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 1 MIU by Mukhtar Enterprises (Reg #093937)
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator Colistimethate sodium 2 MIU Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.		
API Lot No.	HN190202		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T010	T011	T012
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	16-02-2020	17-02-2020	18-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20190058) issued by CFDA China. The certificate is valid till 14-08-2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 02-02-2020 specifying import of 0.5Kg Colistimethate. The invoice is not attested by AD (I&E) DRAP Field office. The firm has submitted copy of DHL invoice (Invoice No. 20HS-091) for the import of drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, and pictures of the petri dishes showing zone of inhibitions following the microbial assay.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The applied formulation to be manufactured by M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi have already been granted approval by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already considered product in 297th meeting are as follows:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	**LISTIM Injection 1 MIU (IV)**
Batch No. of drug product	T010 T011 T012
Case No.	188
Registration Board meeting	297th meeting of Registration Board held on 12th, 13th, 14th & 15th January, 2021

Decision: Approved. Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

1467.	Name, address of Applicant / Marketing Authorization Holder	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry vial section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31773 dated 18-11-2021
	Details of fee submitted	Rs.75,000/- dated 21-10-2021
	The proposed proprietary name / brand name	**Colist 2 MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Colistimethate sodium……2 MIU
	Pharmaceutical form of applied drug	Sterile white to yellowish fine powder filled in transparent glass vials with grey rubber stopper with an aluminium cap
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Injection **(MHRA** Approved)
	For generic drugs (me-too status)	Colistimethate injection 2 MIU by Mukhtar Enterprises (Reg #094757)
	Name and address of API manufacturer.	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its

		description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator Colistimethate sodium 2 MIU Injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Hebei Shengxue Dacheng Co. Ltd. No. 50, Shengxue Road No. 17 Fuqiangxi Road, Luacheng County, Hebei Province P.R China.		
API Lot No.	HN190202		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T013	T014	T015
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	16-02-2020	17-02-2020	18-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20190058) issued by CFDA China. The certificate is valid till 14-08-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 02-02-2020 specifying import of 0.5Kg Colistimethate. The invoice is not attested by AD (I&E) DRAP Field office. Firm has submitted copy of DHL invoice for the import of drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, and pictures of the petri dishes showing zone of inhibitions following the microbial assay.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA

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

Evaluation by PEC:

- The applied formulation to be manufactured by M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi have already been granted approval by Registration Board in its 297th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already considered product in 297th meeting are as follows:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	**LISTIM Injection 2 MIU (IV)**
Batch No. of drug product	T013 T014 T015
Case No.	236
Registration Board meeting	297th meeting of Registration Board held on 12th, 13th, 14th & 15th January, 2021

Decision: Approved. Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding "Review of Colistimethate for Injection" along with submission of requisite fee for pre-registration correction/changes of label claim (if required) as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

1468.	Name, address of Applicant / Marketing Authorization Holder	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the manufacturer firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Hydrocortisone injection section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32572 dated 13-12-2021
	Details of fee submitted	Rs.75,000/- dated 14-10-2021

	The proposed proprietary name / brand name	**Cortef-Zone 100mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 100 mg
	Pharmaceutical form of applied drug	White to off White color, Lyophilized, Sterile Powder filled in Glass Vial as 1's Injection with 2mL Water for Injection further packed in Card board Unit Carton along with Leaflet.
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cortizone injection by Global pharma
	Name and address of API manufacturer.	Symbiotec Pharmalab Private Limited 385/2 Pigdamber, Near Hotel Mashal, Off A. B. Road, Rau, Indore 453331 (M.P) India And Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Solucortef 100mg injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India		
API Lot No.	HSS19432		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	13-04-2020	13-04-2020	15-04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. S-3/2018) issued by Food and drug administration Madhya Pradesh dated 19-12-2018. The certificate is valid till 18-12-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 2Kg hydrocortisone and 100mg working standard. The invoice does not contain any date of import and the invoice is also not attested by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The applied formulation to be manufactured by M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi have already been granted approval by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already considered product in 307th meeting are as follows:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi

Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	BIOCORT 100mg Injection
Batch No. of drug product	T001 T002 T003
Case No.	16
Registration Board meeting	307th meeting of Registration Board held on 8th, 9th & 10th June 2021

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

1469.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the manufacturer firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Hydrocortisone injection section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 32573 dated 13-12-2021
	Details of fee submitted	Rs.75,000/- dated 14-10-2021
	The proposed proprietary name / brand name	**Cortef-Zone 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 250 mg
	Pharmaceutical form of applied drug	White to off White color, Lyophilized, Sterile Powder filled in Glass Vial as 1's Injection with 2mL Water for Injection further packed in Card board Unit Carton along with Leaflet.
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cortizone injection by Global pharma

	Name and address of API manufacturer.	Symbiotec Pharmalab Private Limited 385/2 Pigdamber, Near Hotel Mashal, Off A. B. Road, Rau, Indore 453331 (M.P) India And Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Solucortef 100mg injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Symbiotec Pharmalab Private Limited 385/2 Pigdamber, Near Hotel Mashal, Off A. B. Road, Rau, Indore 453331 (M.P) India And Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India
API Lot No.	HSS19432
Description of Pack (Container closure system)	Glass vial

Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	13-04-2020	13-04-2020	15-04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. S-3/2018) issued by Food and drug administration Madhya Pradesh dated 19-12-2018. The certificate is valid till 18-12-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 2Kg hydrocortisone and 100mg working standard. The invoice does not contain any date of import and the invoice is also not attested by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The applied formulation to be manufactured by M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi have already been granted approval by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already considered product in 307th meeting are as follows:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	BIOCORT 250mg Injection
Batch No. of drug product	T001 T002 T003
Case No.	17
Registration Board meeting	307th meeting of Registration Board held on 8th, 9th & 10th June 2021

Decision: Approved.

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

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**		
1470.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the manufacturer firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Hydrocortisone injection section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 34141 dated 30-12-2021
	Details of fee submitted	Rs.75,000/- dated 14-10-2021
	The proposed proprietary name / brand name	**Cortef-Zone 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 500 mg
	Pharmaceutical form of applied drug	White to off White color, Lyophilized, Sterile Powder filled in Glass Vial as 1's Injection with 2mL Water for Injection further packed in Card board Unit Carton along with Leaflet.
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cortizone injection by Global pharma
	Name and address of API manufacturer.	Symbiotec Pharmalab Private Limited 385/2 Pigdamber, Near Hotel Mashal, Off A. B. Road, Rau, Indore 453331 (M.P) India And Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Solucortef 100mg injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Symbiotec Pharmalab Private Limited 385/2 Pigdamber, Near Hotel Mashal, Off A. B. Road, Rau, Indore 453331 (M.P) India And Symbiotec Pharmalab Private Limited Plot no.5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar-454774, (M.P.), India		
API Lot No.	HSS19432		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	400 vials	400 vials	400 vials
Manufacturing Date	03-2020	03-2020	03-2020

Date of Initiation	13-04-2020	13-04-2020	15-04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. S-3/2018) issued by Food and drug administration Madhya Pradesh dated 19-12-2018. The certificate is valid till 18-12-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 2Kg hydrocortisone and 100mg working standard. The invoice does not contain any date of import and the invoice is also not attested by AD (I&E).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- The applied formulation to be manufactured by M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi have already been granted approval by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already considered product in 307th meeting are as follows:

Applicant firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Manufacturer firm	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Brand Name	BIOCORT 500mg Injection
Batch No. of drug product	T001 T002 T003
Case No.	18
Registration Board meeting	307th meeting of Registration Board held on 8th, 9th & 10th June 2021

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi.**

1471.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 33458 dated 22-12-2021
	Details of fee submitted	Rs.30,000/- dated 18-11-2021
	The proposed proprietary name / brand name	**Trubax Cream 1%w/w**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Terbinafine HCl … 10mg
	Pharmaceutical form of applied drug	Topical Cream
	Pharmacotherapeutic Group of (API)	Allylamine Anti-fungal for topical use
	Reference to Finished product specifications	JP specification
	Proposed Pack size	10 grams
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil Cream by GSK (FDA approved).
	For generic drugs (me-too status)	Lamisil Cream by GSK (Reg. # 084005).
	Evidence of manufacturing facility	Grant of additional section of "Topical semisolid (cream/ointment/gel) vide letter No. F.1-20/2006-Lic (Vol-I) dated 20-07-2020.
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 06-07-2020.
	Name and address of API manufacturer.	Terbinafine HCl: Shandong Boyuan Pharmaceutical Co., Ltd. Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China. 251400
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of API as per zone IV-A conditions Stability study conditions:

		Terbinafine HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence study against the innovator's product i.e. Lamisil Cream by GSK. Pharmaceutical Equivalence have been conducted by performing quality tests (pH, Identification and Assay).
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug product including system suitability, specificity, accuracy, spiking, repeatability & intermediate precision

STABILITY STUDY DATA

Manufacturer of API	Shandong Boyuan Pharmaceutical Co., Ltd. Qiangjin Street, Jibei Economic Development Zone, Jinan, Shandong, China. 251400		
API Lot No.	Terbinafine-HCl: B#: 210105TA		
Description of Pack (Container closure system)	Alu – Tube		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	150 tubes	150 tubes	150 tubes
Manufacturing Date	05 – 2021	05 – 2021	05 – 2021
Date of Initiation	20-05-2021	20-05-2021	20-05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Terbinafine HCl: The firm has submitted copy of DML# Lu20160312 of Shandong Boyuan Pharmaceutical Co., Ltd. Issued by CFDA, valid till 25-04-2026
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Terbinafine-HCl: The firm has submitted copy of attested commercial invoice by AD (I&E) DRAP field office dated 26-02-2021 specifying import of 4.70 Kg of API.
4.	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted

	Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Decision: Approved.

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

1472.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate, Raiwind, Lahore**
	Name, address of Manufacturing site.	M/s Stallion Pharmaceuticals, PVT, LTD. 581-Sundar Industrial Estate, Raiwind Road Lahore, Punjab 54000.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27957 dated 11-10-2021
	Details of fee submitted	Rs.50,000/- dated 20-11-2020
	The proposed proprietary name / brand name	**Imastin 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Imipenem ……. 500mg Cilastatin Sodium Eq. to Cilastatin …… 500mg
	Pharmaceutical form of applied drug	Intravenous Sterile Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection (USFDA Approved)
	For generic drugs (me-too status)	Onem Injection of Global Pharmaceuticals
	GMP status of the Finished product manufacturer	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 22-09-2020, wherein Dry powder injectable Carbapenem section is declared.
	Name and address of API manufacturer.	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the Cilapen Injection by M/s Bosch Pharma by performing quality tests.
	Analytical method validation/verification of product	Method verification studies have submitted

STABILITY STUDY DATA			
Manufacturer of API	M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India		
API Lot No.	KA1007150016		
Description of Pack (Container closure system)	Type II clear Glass Vials.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time:24 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0, 3, 6,9,12,18,24 (Months)		
Batch No.	V6001	V7001	V8001
Batch Size	17,600 vials	8700 vials	4400 vials
Manufacturing Date	10-2016	08-2017	02-2018
No. of Batches	03		
Documents submitted along with stability data.			
	Reference of previous approval of applications with stability study data of the firm (if any)	--	

	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate of M/s Aurobindo Pharma ltd., Unit-V, Plot. No. 79-91, I.D.A, Chemical Zone, pashamylarm, Ptancheru Mandal, Medak Dist, Telangana, India issued by Drugs Control Administration, Telangana, India valid up to 13-10-2017.
	Documents for the procurement of API with approval from DRAP (in case of import).	---
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A

Remarks of Evaluator[II]:

Section#	**Observation**	**Firm's response**
1.1	Differential fee o Rs. 25,000/- shall be submitted.	Firm ha submitted differential fee of Rs. 25000/- vide deposit slip# 98796611724
3.2.S.1	Submitted information does not include details of any buffering agent present in the drug substance.	Firm has referred to section 3.2.S.2.2 of DMF wherein blending with sodium bicarbonate sterile is declared in manufacturing process.
3.2. S.4.1	• Submitted specifications form drug substance manufacturer does not declare content of any buffering agent. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer shall be submitted.	• Not given in DMF part & not recommended by USP as well. • Submitted
3.2.S.4.3	Analytical method verification studies from the drug product manufacturer shall be submitted.	Submitted.
3.2. S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used for the formulation of submitted batches of drug product stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance manufacturer.	Firm has submitted COAs from both drug susbtacne manufacturer and drug product manufacturer for the batch# 1605204528, 1705202345, 1705208644 along with commercial invoices attested by AD DRAP I&E Lahore, dated 08-9-2016, 28-07-2017 & 09-02-2018 respectively.
3.2.S.5	Submit COA of reference standard / working standard including source and lot number which is actually used in the testing of batches of drug substance and drug product submitted in the dossier.	Firm has submitted COAs of USP primary reference standards.
3.2.P.1	Details of reconstitution diluent shall be submitted.	Submitted as Zee-Inject (WFI) of M/s Shazeb pharmaceuticals.

3.2.P.2.2.1	Justification shall be submitted for not performing Pharmaceutical equivalence studies against the innovator product shall be submitted.	Due to unavailability of innovator product of Imipenem and Cilastatin injection in the market, we did our comparative studies with the Cilapen 500 mg Injection of Bosch Pharma which is our brand competitor of Imipenem and Cilastatin.
3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.	Firm has submitted compatibility study with WFI as diluent.
3.2.P.3.2	Relevant information shall be submitted.	Submitted
3.2.P.5.1	Submit drug product specification including limit for filled weight per vial. Justify why the test of "constituted solution" and "particulate matter in injection" is not included in your product specification since these tests are recommended by USP.	Firm has submitted revised drug product analytical procedure as per USP monograph.
3.2.P.5.2	• Submitted details of "Standard preparation" & Sample preparation" in the Assay test are not as per USP monograph. • Details of reference standard of Cilastatin mentioned in the Assay test are not as per USP monograph. • Justify the test of pH in section 3.2.P.5.2 which specifies that reconstitute the sample in 100ml carbon di oxide free distilled water, however USP specifies that reconstitute as directed in the labelling. The labelling of the innovator / reference product does not recommend reconstitution in water. • Justify the use of imipenem + Cilastatin working standard solution for the assay since USP has recommended separate standard preparation for Imipenem as well as Cilastatin for the assay test. • Justify why the calculation formula used for the assay test is different from that specified in USP monograph.	
3.2.P.5.3	Submit analytical method verification studies wherein standard and solution preparation method as recommended by USP monograph, shall be applied.	Firm has submitted revised analytical procedure only
3.2.P.6	Submit details along with COAs of working standard used for the analysis of stability batches of drug product, provided in the dossier.	Firm has submitted COAs of USP primary reference standards.

	3.2.P.8.3	• Documents for the procurement of drug substance with approval from DRAP, for relevant batches used in the formulation of drug product stability batches submitted along with dossier, shall be provided. • Justify non-performance of test of particulate matter during stability studies, as evident from the submitted data. • Justify the performance of Assay test using single standard solution of Impinem+Cilastatin working standard, since USP monograph recommends use of separate standard solution of Imipenem reference standard & Cilastatin ammonium reference standard. • Sample preparation details as evident from submitted raw data sheets of complete stability studies is not asper USP monograph, since firm has diluted the sample vial with 5ml distilled water whereas USP monograph recommends reconstitution of sample vial with in a volume of saline TS, accurately measured, corresponding to the volume of solvent specified in the labelling. • Justify the performance of Assay analysis on different UV detector wavelengths than that recommended by USP monograph i.e., 254nm. • Complete batch manufacturing record for the stability batches of drug product shall be submitted.	We placed three consecutive batches of Primaxin Sterile Dry Powder lnjection 500 mg V6001, V7001 and V8001 in 2016, 2017 and 2018 for accelerated stability study at 40°C ± 2°C / 75% ± 5%RH and Real time at 30°C ± 2°C / 65% ± 5%RH in which the analyst performs the tests with different method of preparation of sample and standard solutions and at different wavelength, which is not according to the USP monograph Due to this reason, we re-placed three consecutive batches of Primaxin Sterile Dry Powder lnjection 500mg V2001, V2002 and V2003 in 2022 for the accelerated stability study which will be completed in October 2022 and for shelf life stability which will be completed in April 2024 and their testing is according to the latest USP monograph. The Results of these ongoing stabilities are submitted.

Decision: Deferred for following:

- **Justification for proposing "Water for injection" WFI as reconstitution diluent for applied formulation.**
- **Submission of analytical method verification studies of drug product as per USP monograph.**
- **Evaluation of revised stability data of drug product along with submission of complete details of drug substance i.e., COAs, documents confirming import of dug substance, for the relevant batch no. used to manufacture recently submitted drug product stability batches, full fee of Rs. 75,000/- for revision of stability studies data as per notification No.F.7-11/2012- B&A/DRAP dated 13-07-2021.**

1473.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 01-04-2021.

	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Capsule (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying capsule (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32724 dated 01-12-2021
	Details of fee submitted	Rs.50,000/- dated 19-05-2021 & Rs.25,000/- dated 26-05-2021
	The proposed proprietary name / brand name	**Genfixim 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime as trihydrate……400mg
	Pharmaceutical form of applied drug	Hard gelatin capsule size # 0 with blue colored body and cap having white to yellow colored powder
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	1x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real

		time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cebosh capsule.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00244-11/322/2017 00244-11/344/2017 00244-07/146/2018		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180010	180042	180059
Batch Size	100,000 capsule	10,000 capsule	10,000 capsule
Manufacturing Date	02-2018	07-2018	09-2018
Date of Initiation	17-03-2018	07-08-2018	16-10-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP dated 11-01-2019 based on the inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 09-01-2018 specifying purchase of 7Kg Cefixime (compacted) Lot No. 00244-11/322/2017 and 43 Kg cefixime (compacted) Lot No. 00244-11/344/2017. Firm has submitted copy of commercial invoice dated 31-08-2018 specifying purchase of 50Kg Cefixime (compacted) Lot No. 00244-07/146/2018.

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

Evaluation by PEC: Registration Board in its 316th meeting while considering the applied formulation to be manufactured by M/s Cunningham Pharmaceuticals against the applicant of M/s PDH laboratories has decided as under:

Deferred for following:

- Submission of stability study data of three commercial batches of the drug product in which product testing has been conducted as per the product specification approved by Registration Board in its 313rd meeting and notified vide No.F.14-1/2022-PEC dated 14th March 2022.
- Firm shall submit the fee of Rs. 30,000 for revision in stability data, as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Response by the firm:

Firm has submitted stability study data of 3 newly manufactured batches in which product testing has been performed as per the monograph for cefixime capsule approved by Registration Board for 6 months. The details of the newly manufactured batches is as under:

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00244-10/193/2021		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	220026
Batch Size	2000 Capsule	2000 Capsule	50,000 capsule
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	15-03-2022	15-03-2022	28-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP dated 11-01-2019 based on the inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 03-12-2021 specifying purchase of 7Kg Cefixime (compacted)
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Decision: Approved with Manufacturer's specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **The firm shall submit fee of Rs. 75,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**		

b. Deferred cases

1474.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JASM Pharmaceuticals (Pvt) Ltd. Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.**
	Name, address of Manufacturing site.	M/s JASM Pharmaceuticals (Pvt) Ltd. Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Evidence of availability of manufacturing section.	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup, Cream Ointment (General Sections) Approved
	Dy. No. and date of submission	Dy.No 32162 dated 24-11-2021
	Details of fee submitted	Rs.30,000/- dated 04-10-2021
	The proposed proprietary name / brand name	**Adovel Suspension 100 mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ibuprofen…….100 mg
	Pharmaceutical form of applied drug	Oral Suspension
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	Proposed Pack size	90 ml / bottle or as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA

	For generic drugs (me-too status)	Fenbro suspension of M/s Stanley Pharmaceuticals (Reg.#04332)
	GMP status of the Finished product manufacturer	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup, Cream Ointment (General Sections) Approved
	Name and address of API manufacturer.	M/s Zenith Chemical Industries (Pvt) Limited. Moza Dhonday, Jia Baga Raiwind Kahna Road Raiwind Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Brufen Suspension 100 mg/5mL.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s **Zenith Chemical Industries (Pvt) Limited.** Moza Dhonday, Jia Baga Raiwind Kahna Road Raiwind Pakistan.
API Lot No.	ZIBU20-032
Description of Pack (Container closure system)	90 ml / bottle packed in a Unit Carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 & 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	P03	P15	P33
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	04-2021	04-2021	05-2021
Date of Initiation	28-04-2021	30-04-2021	01-05-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate Ref No. 141/2019-Drap (AD-813875--228) issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Manual record has been submitted with one reading in a day
1475.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JASM Pharmaceuticals (Pvt) Ltd Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.**
	Name, address of Manufacturing site.	M/s JASM Pharmaceuticals (Pvt) Ltd Address: Plot # 4A, Export Processing street, Risalpur Industrial Estate, Nowshera. Khyber Pukhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Evidence of availability of manufacturing section.	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup, Cream Ointment (General Sections) Approved
	Dy. No. and date of submission	Dy. No 32164 dated 24-11-2021
	Details of fee submitted	Rs.30,000/- dated 10-11-2021
	The proposed proprietary name / brand name	**Adovel Suspension 200 mg/5ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ibuprofen ……. 200 mg
	Pharmaceutical form of applied drug	Oral **Suspension**
	Pharmacotherapeutic Group of (API)	**NSAID**
	Reference to Finished product specifications	BP
	Proposed Pack size	90 ml / bottle or as per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Fenbro suspension of M/s Stanley Pharmaceuticals
	GMP status of the Finished product manufacturer	New license granted on 29/09/2020 Tablet, Capsule, Dry Powder, Liquid Syrup , Cream Ointment (General Sections) Approved
	Name and address of API manufacturer.	M/s **Zenith Chemical Industries (Pvt) Limited.** Moza Dhonday, Jia Baga Raiwind Kahna Road Raiwind Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Brufen DS Suspension .
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s **Zenith Chemical Industries (Pvt) Limited.** Moza Dhonday, Jia Baga Raiwind Kahna Road Raiwind Pakistan.		
API Lot No.	ZIBU20-032		
Description of Pack (Container closure system)	90 ml / bottle packed in a Unit Carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3 & 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	P09	P22	P37
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	04-2021	05-2021	05-2021
Date of Initiation	29-04-2021	01-05-2021	03-05-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate Ref No. 141/2019-Drap(AD-813875--228) issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Manual record has been submitted with one reading in a day

Firm's response:
Remarks of Evaluator:

Section#	Observation	Firm's response
3.2.S.4.2	• Analytical procedure applied by the drug substance manufacturer shall be submitted.	Submitted.
3.2.P.1	• Justify the types & quantities of preservatives used in the proposed formulation.	Firm has stated that the selection of excipient was based upon the innovator product & the quantity of each excipient was justified within the allowable limits for the desired function of the excipient as declared in the Handbook of pharmaceutical excipients. Whereas the reference product does not contain methyl paraben & propyl paraben as proposed in the applied formulation.
3.2.P.2	Submit drug excipient compatibility studies data since, the innovator	Not submitted.

	product referred by firm does not contain the excipients proposed in the applied formulation.	
3.2.P.5.2	• Procedure for sample dilution preparation is not as per the BP monograph for "Ibuprofen oral suspension."	Firm has submitted revised analytical procedure as per BP monograph.
3.2.P.8.3	• The calculation formula applied for the Assay calculation is not as per that recommended by BP monograph of "Ibuprofen oral suspension" • Complete raw data sheets, wherein details of sample and standard dilution making is evident, shall be submitted. • Test of preservative effectiveness has not been performed during stability studies.	• Firm has submitted the calculation formula wherein determination of "weight per ml" as recommended by the BP monograph is not evident. • Submitted raw data sheet still not declare the actual quantities of standard and sample weighed for the preparation of relevant solutions. • Firm has submitted preservative effectiveness studies at the most recent time point (October 2021) of accelerated & long-term stability studies, which is earlier to the communication of this observation.

Decision of 316th meeting: Registration Board deferred both the applications of "Adovel Suspension 200 mg/5ml" & "Adovel Suspension 100 mg/5ml" for submission of Assay results at the next time point of long-term stability studies, as per the method & calculation formula recommended by the BP monograph of "Ibuprofen suspension".

Firm's response: Firm has submitted results of 12th month time point of long term stability studies for stability batches for both Adovel suspension 100mg/5ml & Adovel suspension 200mg/5ml as per BP monograph.

Decision: Registration Board approved th applications of Adovel Suspension 100 mg/5ml & Adovel Suspension 200 mg/5ml.

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

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New Section

M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore
The Central Licensing Board in its 286th meeting held on 11th May, 2022 has considered and approved the grant of Drug Manufacturing License to M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore by way of Formulation vide approval letter No. F. 1-10/2012-Lic dated 7th June, 2022 with following (06) sections.

S No.	Section
1	Dry Powder Suspension (Cephalosporin) Section
2	Capsule (Cephalosporin) Section
3	Dry Powder Injection (Cephalosporin) Section

1476.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31335 dated 02-11-2022
	Details of fee submitted	PKR 30,000/-: dated 29/10/2022
	The proposed proprietary name / brand name	**Welcef 500mg IV injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone…500mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Rocephin injection 500mg IV by M/s F.Hoffman-La Roche Ltd. Basel, Switzerland, Reg. No.00843
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. SinopharmWeiqida Pharmaceutical Co., Ltd. Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C /75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Oxidil injection 500mg IV.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.		
API Lot No.	Q012202234		
Description of Pack (Container closure system)	1x10ml vial containing Ceftriaxone for Injection with reconstituent Diluent.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCA001	TCA002	TCA003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	12-04-22	13-04-22	14-04-22
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by NMPA of China valid till 05/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Ceftriaxone Sodium. • Copy of letter No. 3855/2022/DRAP dated 29/March/2022 is submitted where in the permission to import different APIs including Ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. • Invoice # W220222, DATE: 14-March-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

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

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4.1	Justification shall be submitted for difference in specifications of Assay test between the drug substance manufacturer and drug product manufacturer for Ceftriaxone sodium.	Firm has submitted revised specifications as per drug substance manufacturer.
3.2.S.5	COA of reference/working standard used for the drug substance analysis shall be submitted.	Submitted
3.2.S.7.3	Long term stability studies data shall be submitted as per Zone IVA.	Submitted from M/s Sinopharm, as per Zone IVa.
3.2.P.1	• Proposed Quantity of Ceftriaxone sodium per unit vial shall be justified against the label claim for Ceftriaxone. • Details of accompanying reconstitution diluent shall be submitted.	• Firm has justified the weight per unit vial according to the potency of Ceftriaxone determined during drug substance analysis. • Firm has referred WFI as diluent for applied formulation.
3.2.P.2.2.1	Justification shall be submitted for performing Pharmaceutical equivalence studies against the Oxidil injection instead of the innovator product i.e., Rocephin Injection.	Frim has submitted Pharmaceutical equivalence studies against the Rocephin Injection 500mg.
3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.	Firm has submitted compatibility study with water for injection as diluent.
3.2.P.5.1	Drug product specifications does not include limits for Assay test for sample solution 1.	Firm has referred to drug substance analysis for the results of sample solution 1.
3.2.P.5.2	Complete method of sample solution preparation shall be submitted for the Assay test.	Firm has submitted drug product analytical method with details of sample solution preparation.
3.2.P.6	COA of reference/working standard used for analysis of stability batches shall be submitted	Submitted.
3.2.P.8.3	• Documents confirming import of drug substance approved by DRAP shall be submitted. • Dispensed quantity of Ceftriaxone sodium shall be justified against the label claim.	• Firm has submitted clearance no. E-533464883684 for 500Kg of Ceftriaxone sodium issued in name of M.s Medisave by AD I&E DRAP, Lahore. • Firm has justified the weight per unit vial according to the potency of Ceftriaxone determined during drug substance analysis.

Decision: Approved.

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

1477.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No 31334 dated 02-11-2022
	Details of fee submitted	PKR 30,000/-: dated 29/10/2022
	The proposed proprietary name / brand name	**Welcef 250mg IV injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone…250mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Oxidil injection 250mg of M/s Sami Pharma
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. SinopharmWeiqida Pharmaceutical Co., Ltd. Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C /75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and

		its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Oxidil injection 250mg IV.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.		
API Lot No.	Q012202234		
Description of Pack (Container closure system)	1x10ml vial containing Ceftriaxone for Injection with reconstituent Diluent.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCT001	TCT002	TCT003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	05-04-22	06-04-22	07-04-22
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by NMPA of China valid till 05/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Ceftriaxone Sodium. • Copy of letter No. 3855/2022/DRAP dated 29/March/2022 is submitted where in the permission to import different APIs including Ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. • Invoice # W220222, DATE: 14-March-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator[II]:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1478.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Lahore. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate, Raiwind road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31340 dated 02-11-2022
	Details of fee submitted	PKR 30,000/-: dated 29/10/2022
	The proposed proprietary name / brand name	**Welcef 1gm IV injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone…1gm
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Rocephin injection 1g IV by M/s F.Hoffman-La Roche Ltd. Basel, Switzerland, Reg. No.008435
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. SinopharmWeiqida Pharmaceutical Co., Ltd. Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C /75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Oxidil injection 1gm IV.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sinopharm Weiqida Pharmaceutical Co., Ltd. Address: Pharmaceutical Industrial Park, Economic & Technological Development Zone, Datong, Shanxi, China 037300.		
API Lot No.	Q012202234		
Description of Pack (Container closure system)	Glass vial containing Ceftriaxone for Injection		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCA001	TCA002	TCA003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	09-04-22	10-04-22	11-04-22
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SX20180229 issued by NMPA of China valid till 05/06/2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Ceftriaxone Sodium. • Copy of letter No. 3855/2022/DRAP dated 29/March/2022 is submitted where in the permission to import different APIs including Ceftriaxone sodium for the purpose of test/analysis and stability studies is granted. • Invoice # W220222, DATE: 14-March-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4.1	Justification shall be submitted for difference in specifications of Assay test between the drug substance manufacturer and drug product manufacturer for Ceftriaxone sodium.	Firm has submitted revised specifications as per drug substance manufacturer.
3.2.S.5	COA of reference/working standard used for the drug substance analysis shall be submitted.	Submitted
3.2.S.7.3	Long term stability studies data shall be submitted as per Zone IVA.	Submitted from M/s Sinopharm, as per Zone IVa.
3.2.P.1	• Proposed Quantity of Ceftriaxone sodium per unit vial shall be justified against the label claim for Ceftriaxone. • Details of accompanying reconstitution diluent shall be submitted.	• Firm has justified the weight per unit vial according to the potency of Ceftriaxone determined during drug substance analysis. • Firm has referred WFI as diluent for applied formulation.
3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.	Firm has submitted compatibility study with water for injection as diluent.
3.2.P.5.1	Drug product specifications does not include limits for Assay test for sample solution 1.	Firm has referred to drug substance analysis for the results of sample solution 1.
3.2.P.5.2	Complete method of sample solution preparation shall be submitted for the Assay test.	Firm has referred to drug substance analysis for the results of sample solution 1.
3.2.P.6	COA of reference/working standard used for analysis of stability batches shall be submitted	Submitted.
3.2.P.8.3	• Documents confirming import of drug substance approved by DRAP shall be submitted. • Dispensed quantity of Ceftriaxone sodium shall be justified against the label claim.	• Firm has submitted clearance no. E-533464883684 for 500Kg of Ceftriaxone sodium issued in name of M.s Medisave by AD I&E DRAP, Lahore. • Firm has justified the weight per unit vial according to the potency of Ceftriaxone determined during drug substance analysis.

Decision: Approved.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration letter will be issued after verification of the loan letter by M/s Medisave Pharmaceuticals.**		
1479.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy. No 29614 dated 18-10-2022
	Details of fee submitted	Rs.30,000/- dated 13-09-2022
	The proposed proprietary name / brand name	**Iron Plus 100mg/5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule contains: Iron (III) hydroxide sucrose complex eq. to elemental Iron ……. 100mg
	Pharmaceutical form of applied drug	Amber color Ampoule.
	Pharmacotherapeutic Group of (API)	(Anti-anaemic)
	Reference to Finished product specifications	BP
	Proposed Pack size	5ml×05's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Venofer 100mg/5ml by M/s Vifor Pharma, approved by TGA Australia
	For generic drugs (me-too status)	Venofer 100 mg/5ml by M/s OBS Reg. No. 085031
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	M/s SYMED LABS LIMITED, UNIT-II, Plot No. 25/B, Phase-III, IDA, Jeedimetla (Village), Quthbullapur (Mandal) Medchal- Malkajgiri (Dist)-500 055, Telangana, INDIA.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Venofer injection
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s SYMED LABS LIMITED, UNIT-II, Plot No. 25/B, Phase-III, IDA, Jeedimetla (Village), Quthbullapur (Mandal) Medchal- Malkajgiri (Dist)-500 055, Telangana, INDIA.		
API Lot No.	21P (B) 0100718		
Description of Pack (Container closure system)	Glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2. S.4.1	Drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies Shall Be Submitted from M/s May & Baker.	Submitted.
3.2.S.4.4	COA of relevant batch of API from drug substance manufacturer shall be submitted used for manufacturing of drug product trial batches declaring the potency in terms of iron content	Firm has submitted COA of batch#21P (B) 0100718 from M/s Symed Labs Limited.
3.2.P.1	Justify the quantity of Iron sucrose complex per ampoule against the label claim of elemental iron.	Firm has stated that each ampoule contains 1984mg of iron sucrose complex eq. to 100mg elemental iron, based upon the potency of drug substance.
3.2.P.5.1	Submitted drug product specifications does not include test of sucrose content.	Firm has submitted revised drug product specifications including test of sucrose content.
3.2.P.8	• Complete batch manufacturing record of three stability batches shall be submitted. • GMP certificate of the drug substance manufacturer shall be submitted. • Documents confirming procurement of drug substance shall be submitted.	• Firm has submitted trial batch manufacturing record for three stability batches. • Firm has submitted copy of GMP certificate# 84086/TS/2022 issued by DCA Telangana, valid till 24-03-2023. • Frim has submitted copy of letter from M/s Global Pharmaceuticals, for the grant of loan of API's including Iron sucrose complex for stability and registration purpose. • Firm has submitted copy of commercial invoice in name of M/s Global Pharmaceuticals for import of 300Kg of Iron sucrose, attested by AD I&E DRAP, Islamabad dated 07-05-2018.

Decision: Approved. Registration letter will be issued after verification of the loan letter by M/s Global Pharmaceuticals.

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

1480.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32816 dated 15-11-2022
	Details of fee submitted	PKR 30,000/-: dated 29/10/2022
	The proposed proprietary name / brand name	**MAGNIX 2gm IV/IM injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperzone sodium eq. to Cefoperazone …… 1000mg Sulbactam sodium eq. to Sulbactam ……. 1000mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	JP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cebac 2G injection IM/IV by M/s Bosch pharmaceutical (Pvt) Ltd., USFDA Approved. Reg. No.073420
	For generic drugs (me-too status)	Sulperazone 2g injection by M/s Pfizer
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against t Cebac 2Gm injection IM/IV by M/s Bosch pharmaceutical (Pvt) Ltd.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.		
API Lot No.	1093EJ81NE		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCR001	TCR002	TCR003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	09-04-22	10-04-22	11-04-22
No. of Batches	03		

1481.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No 32815 dated 15-11-2022
	Details of fee submitted	PKR 30,000/-: dated 29/10/2022
	The proposed proprietary name / brand name	**MAGNIX 1gm IV/IM injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefoperzone sodium eq. to Cefoperazone …….. 500mg Sulbactam sodium eq. to Sulbactam ……. 500mg Sulbactam
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotics
	Reference to Finished product specifications	In-house
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cebac 1G injection IM/IV by M/s Bosch pharmaceutical (Pvt) Ltd., USFDA Approved. Reg. No.073420
	For generic drugs (me-too status)	Sulperazone 1g injection by M/s Pfizer
	GMP status of the Finished product manufacturer	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Name and address of API manufacturer.	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been submitted against the Cebac 1Gm injection IM/IV by M/s Bosch pharmaceutical.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s. Qilu Antibiotics Pharmaceutical Co. Ltd. 849 Dongjia Town, Licheng District Jinan City PR China.		
API Lot No.	1093EJ81NE		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TCS001	TCS002	TCS003
Batch Size	500Vials	500Vials	500Vials
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	05-04-22	06-04-22	07-04-22
No. of Batches	03		

Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
9.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter from M/s Medisave Pharmaceuticals in name of M/s Wimits Pharmaceuticals for "Approval of Loan" of Cefoperazone sodium/Sulbactam sodium dated 18-03-2022. • Copy of commercial Invoice # JTRF210908-MQ in name of M/s Medisave Phamraceuticals, attested by AD I&E Lahore dated 01-10-2021 for import of 100 KG Cefoperazone sodium + Sulbactam sodium.
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr.#	Observations	Firm's response
1.5.6	The said section mentions the drug product specifications as "In-house" whereas section 3.2.P.5.1 declares the drug product specifications as per JP monograph. Clarification shall be submitted in this regard.	Firm has submitted revised section 1.5.6 declaring drug product specifications as per JP for both strengths.
1.6.5	Valid copy of GMP certificate/DML of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate no. SD20180660 issued by CFDA valid till 008-02-2023
3.2.P.1	Details of accompanying reconstitution diluent shall be submitted.	Firm has referred to WFI as reconstitution diluent.
3.2.P.2.2.1	Justification shall be submitted for not performing test of pH and water Content in Pharmaceutical equivalence studies.	Firm has submitted performance of test of pH and water content in Pharmaceutical equivalence studies.
3.2.P.2.6	Compatibility studies with reconstitution diluent shall be submitted.	Compatibility studies with WFI has been submitted for both strengths.
3.2.P.5.2	The submitted analytical procedure does not mention use of internal standard solution in Assay test as recommended by JP monograph. Clarification shall be submitted in this regard.	It is submitted that the system suitability test has been performed during analytical method verification studies as per JP monograph wherein internal standard solution was used along with standard and sample solutions. Firm has also submitted revised analytical procedure.
3.2.P.6	COA of reference/working standard of "Sulbactam" shall be submitted.	Submitted.
3.2.P.8	Justification shall be submitted for manufacturing of trial batches sin April 2022, whereas section approval was granted on 07-06-2022.	Inspection was conducted on 21st March 2022 and sections were approved as per inspection report.

Decision: Registration Board approved the applications of MAGNIX 2gm IV/IM injection & MAGNIX 1gm IV/IM injection. Registration letter will be issued after verification of the loan letter by M/s Medisave Pharmaceuticals and submission of fee of Rs. 75,000/- for each strength for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

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

1482.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore**
	Name, address of Manufacturing site.	M/s May & Baker Pharmaceuticals (Pvt.) Ltd. 45 Km, Thokar Multan road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Evidence of Manufacturing facility	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Dy. No. and date of submission	Dy.No 30776 dated 31-10-2022
	Details of fee submitted	Rs. 30,000/- dated 31-10-2022
	The proposed proprietary name / brand name	**C-Coline 1gm/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampoule Contains: Citicoline Sodium as Citicoline …… 1gm
	Pharmaceutical form of applied drug	Liquid Injection
	Pharmacotherapeutic Group of (API)	Psychostimulant and nootropic
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by AIFA of Italy
	For generic drugs (me-too status)	Citolin innjection by M/s Global Pharma Reg. No. 030541
	GMP status of the Finished product manufacturer	Issuance of DML vide letter no. F.1-10/2019-Lic. Dated 29-04-2022 for sections of Injectable ampoule (General), Capsule section (general), Dry powder suspension section (general), Dry powder vial section (general)
	Name and address of API manufacturer.	M/s Xinxiang Pharmaceutical Co., Ltd No.30, Jianshe West Road, Xinxiang City, Henan, China. 453002.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Citolin innjection by M/s Global Pharma.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Xinxiang Pharmaceutical Co., Ltd No.30, Jianshe West Road, Xinxiang City, Henan, China. 453002.		
API Lot No.	ZJ200803		
Description of Pack (Container closure system)	Glass ampoules		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 01	Trial 02	Trial 03
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	03-2022	03-2022	03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate# HA20180047 issued by CFDA valid till 21-08-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted "Loan letter for API" Ref# G/2022/786 from M/s Global Pharmaceuticals dated 22-02-2022 for the applied product. Frim has also submitted commercial invoice attested by AD I&E Islamabad dated 09-12-2020 in name of M/s Global Pharmaceuticals for Citicoline sodium.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2. S.4.1	Drug Substance Specifications, Analytical Procedure & Analytical Method Verification Studies shall be submitted from M/s May & Baker as per USP monograph.	Firm has submitted analytical procedure as per USP monograph for Citicoline sodium.
3.2.P.3.2	Manufacturing process shall mention step of terminal sterilization.	Firm has submitted revised manufacturing method with step of terminal sterilization.
3.2.P.5.3	Performance of specificity & robustness parameter shall be submitted in analytical method validation studies.	Submitted.
3.2.P.8	• Documents confirming procurement of drug substance with approval of DRAP I & E office shall be submitted. • Submitted trial manufacturing records have not been signed.	• Firm has submitted signed trial manufacturing records.

Decision: Approved. Registration letter will be issued after verification of the loan letter by M/s Global Pharmaceuticals.

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

1483.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of additional section vide letter no. F.1-1/86-Lic (Vol-V) dated 07-06-2022 for Oral liquid section (General)
	Dy. No. and date of submission	Dy. No 27453 dated 28-09-2022
	Details of fee submitted	Rs.30,000/- dated 05-04-2022
	The proposed proprietary name / brand name	**PD-Fen Syrup 0.25mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Pizotifen Malate…….0.25mg
	Pharmaceutical form of applied drug	Liquid Syrup
	Pharmacotherapeutic Group of (API)	Other antimigraine preparations
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by AEMPS of Spain
	For generic drugs (me-too status)	Mosegar syrup by M/s Novartis Pharma Reg. No. 006282
	GMP status of the Finished product manufacturer	Panel inspection dated 03-1-2022 recommends renewal of DML
	Name and address of API manufacturer.	M/s Suzhou Homesun Pharmaceutical Co., Ltd No. 12 Xiexing West Roas, taicang City, Jiangsu province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Mosegor syrup by M/s Novartis Pharma.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Suzhou Homesun Pharmaceutical Co., Ltd No. 12 Xiexing West Roas, taicang City, Jiangsu province, China.
API Lot No.	20201026
Description of Pack (Container closure system)	Amber colour Glass bottle
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 003	Trial 004	Trial 005
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	11-2021	11-2021	11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate# HA20180047 issued by CFDA valid till 21-08-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice no. 0105SLT2012401-2 attested by AD I&E DRAP dated 26-01-2021 for import of 24gm of Pizotifen malate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator:

Section#	Observations	Firm's response
1.5.3	Submit the strength/concentration of applied formulation as per innovator product in terms of mg/ml and considering the equivalency factor for hydrogen malate along with submission of fee for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted revised label claim: "Each 5ml contains: Pizotifen as hydrogen malate ……. 0.25mg"
3.2. S.4.3	Drug Substance Analytical Method Verification Studies shall include performance of specificity and accuracy parameter.	Submitted.
3.2.P.1	Justify the prosed quantity of Pizotifen malate per unit considering equivalency factor for hydrogen malate	Firm has submitted justification based upon the theoretical factor for the malate salt form calculated on basis of molecular weight.
3.2.P.5.2	Submit drug product analytical procedure.	Submitted.
3.2.P.5.4	Submit signed batch analysis certificates for the trial batches.	Submitted.
3.2.P.5.6	Justification/reference shall be submitted for the limits of test of pH and viscosity.	It is submitted that during the product development phase, we have developed the testing specifications of PD-Fen (Pizotifen) Syrup by comparing it with Competitor product (Mosegor (Pizotifen) Syrup),

		manufactured by Novartis Pharmaceuticals. The test limits of pH and viscosity are established by keeping in view the nature of the excipients and also with respect to the competitor product, available in the market. The pharmaceutical equivalence is submitted.
3.2.P.8	• Submitted invoice is of different batch no. of drug substance from that submitted in section 3.2. S.4.4. • Submit batch manufacturing record for stability batches. • Justification shall be submitted for applying UV spectrophotometric method for the performance of Assay test. • Justification shall be submitted for the production of trial batches before the grant of "Oral liquid section."	• Firm has submitted commercial invoice of relevant batch#20201026 attested by AD I&E DRAP Lahore dated 26-01-2021. • Firm has submitted trial batch manufacturing record for three stability batches. • It is submitted that the product is developed on In-house specifications. At the time of product development phase, we have developed the analytical method of PD-Fen Syrup 0.25mg/5ml on UV spectrophotometer for the performance of assay test. The compliance of this method is ensured through analytical method validation (provided with the dossier). The developed method has been validated statistically for their specificity, linearity, accuracy and precision as per guidelines. • Please be informed that all trial batches are developed in R&D Lab (Batch size: 2.40 Liters).

Decision: Deferred for following:

- **Revision of drug product analytical procedure for assay test on basis of HPLC method and submission of performance of next time point of long term stability studies as per revised HPLC method along with analytical metghod validation studies.**
- **Evidence of approval of R&D lab from CLB.**

New section:

1484.	Name, address of Applicant / Marketing Authorization Holder	M/s **City Pharmaceuticals Laboratories** PLOT # 12-A, I-5 SECTOR 5, New Survey No. 276, Korangi Industrial AREA Karachi Pakistan
	Name, address of Manufacturing site.	M/s **City Pharmaceuticals Laboratories** PLOT # 12-A, I-5 Sector 5, New Survey No. 276, Korangi Industrial Area Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 31471 dated 02-11-2022
	Details of fee submitted	Rs. 30,000/- dated 28-10-2022
	The proposed proprietary name / brand name	**Tyno 600mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Amoxicillin Sodium Eq. to Amoxicillin ……. 500mg Potassium Clavulanate Eq. to Clavulanic Acid …… 100mg
	Pharmaceutical form of applied drug	Powder for solution for injection / infusion

	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Augmentin IV Powder for injection/infusion by M/s **Biopharma S.r.l., Via delle Gerbere 22/30, 00134 Santa Palomba, Roma - Italy** , MHRA Approved.
	For generic drugs (me-too status)	ZEEMOX 500mg Injection by M/s Searle Pakistan, Reg. No. 075070
	Evidence of manufacturing facility	New section granted for Dry powder injection Penicillin
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 29-12-2021.
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co.,Ltd Address: Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Augmentin 600mg IV by GSK Pakistan by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co.,Ltd Address: Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China		
API Lot No.	47SA2004012		
Description of Pack (Container closure system)	Glass vial with rubber stoper and seal (1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TY-001	TY-002	TY-003
Batch Size	900 Vials	900 Vials	900 Vials
Manufacturing Date	08-2021	08-2021	08-2021
No. of Batches	03		

1485.	Name, address of Applicant / Marketing Authorization Holder	M/s **City Pharmaceuticals Laboratories** PLOT # 12-A, I-5 SECTOR 5, New Survey No. 276, Korangi Industrial AREA Karachi Pakistan
	Name, address of Manufacturing site.	M/s **City Pharmaceuticals Laboratories** PLOT # 12-A, I-5 Sector 5, New Survey No. 276, Korangi Industrial Area Karachi Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 18011 dated 21-06-2022
	Details of fee submitted	Rs.30,000/- dated 06-06-2022
	The proposed proprietary name / brand name	**Tyno 1.2gm IV injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Amoxicillin sodium eq. to Amoxicillin ……. 1000mg Potassium Clavulanate eq. to Clavulanic acid. …… 200mg
	Pharmaceutical form of applied drug	Powder for solution for injection / infusion
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Augmentin IV 1.2 gm Powder for injection/infusion by M/s **Biopharma S.r.l., Via delle Gerbere 22/30, 00134 Santa Palomba, Roma - Italy** , MHRA Approved.

	For generic drugs (me-too status)	ZEEMOX 1.2gm Injection by M/s Searle Pakistan, Reg. No. 075970
	Evidence of manufacturing facility	New section granted for Dry powder injection Penicillin
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 29-12-2021.
	Name and address of API manufacturer.	Sinopharm Weiqida Pharmaceutical Co.,Ltd Address: Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Augmentin 1.2gm IV by GSK Pakistan by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Sinopharm Weiqida Pharmaceutical Co.,Ltd Address: Economic & Technological Development Zone, First Medical Zone, Datong, Shanxi, China
API Lot No.	47SA2004012
Description of Pack (Container closure system)	Glass vial with rubber stoper and seal (1's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TN-001	TN-002	TN-003
Batch Size	900 Vials	900 Vials	900 Vials
Manufacturing Date	08-2021	08-2021	08-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sinopharma:** Copy of DML No. Jin 20160008 issued by CFDA valid till 17-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Invoice # EX/3198498 Dated 21-10-2020 is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	We have maintained manual logs of all tests.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4	• Submit drug substance specifications, analytical procedure and analytical method verification studies from M/s City Pharmaceuticals. • Submitted analytical method for Assay test from drug substance manufacturer is not as per BP monograph. Justification shall be submitted in this regard.	Although drug substance manufacturer has not used the method of testing in accordance to BP but we at City Pharmaceuticals have used BP method of testing for releasing the material and has submitted drug substance specifications, analytical procedure and analytical method verification studies as per BP monograph.
3.2.S.4.4	Results of water content test are out of limits in the COA of drug substance submitted from M/s City Pharmaceuticals.	It was a typo error and firm has submitted revised COA for drug substance analysis from M/s City Pharmaceuticals.
3.2.P.1	• Justify the proposed weight of drug substance per unit vial against the label claim. • Description of the reconstitution diluent shall be submitted.	Firm has submitted fill weight calculations based upon percentage potency of Drug substance. Water for injection has been referred as reconstitution diluent.
3.2.P.2.6	Compatibility study with reconstitution diluent shall be submitted.	Submitted with WFI
3.2.P.5.2	Justification shall be submitted for mentioning Potassium clavulanate working standard in Assay test	Firm has submitted COA of USP reference standard of Clavulanate Lithium.

	whereas BP monograph has recommended reference standard of Lithium clavulanate.	
3.2.P.8.3	• Documents confirming import of drug substance with the approval of DRAP I&E shall be submitted. • Dispensed quantity of the drug substance shall be justified against the potency determined during drug substance analysis. • HPLC chromatograms and raw data sheets shall be submitted for complete stability studies of both accelerated and long term conditions till 6 month time point.	• Firm has submitted copy of commercial Invoice # EX/3198498 attested by AD DRAP I&E Karachi dated 24-11-2020 for import of "Amoxicllin + Potassium Clavulanate sterile". • Firm has submitted fill weight calculations based upon percentage potency of Drug substance. • Firm has submitted analytical record for complete stability studies.

Decision: Registration Board approved the applications of Tyno 600mg IV Injection & Tyno 1.2gm IV injection with change of brand name.

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

- **M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad**

The Central Licensing Board in its 287th meeting held on 24th June, 2022 has considered and approved the grant of additional section of "Liquid Syrup (General)" to M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad.

1486	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Caraway Pharmaceuticals. Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 09-03-2020
	Evidence of approval of manufacturing facility	GMP certificate issued on basis of inspection conducted on 09-03-2020 declares availability of Liquid injection ampoule section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30342 dated 26-10-2022
	Details of fee submitted	Rs.30,000/- dated 18-10-2022
	The proposed proprietary name / brand name	**Cara-Gix 5mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Loratadine…..…5mg
	Pharmaceutical form of applied drug	Oral (Liquid Syrup)

	Pharmacotherapeutic Group of (API)	H1-receptor antagonist
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Exigentin Syrup (Reg.# 047263) of M/s Martin-Dow, (Pvt.) Limited Pakistan
	Name and address of API manufacturer.	M/s Morepen Laboratories Limited, Malkumajra (Morepen Village), Baddi Nalagarh Road, Solan Dostrict, Himachal Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5%RH RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5%RH for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the comparator product of Exigentin Syrup of M/s Martin-Dow, (Pvt.) Limited Pakistan
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA	
Manufacturer of APIs	M/s Morepen Laboratories Limited, Malkumajra (Morepen Village), Baddi Nalagarh Road, Solan Dostrict, Himachal Pradesh, India
API Lot No.	LH10B-0708
Description of Pack	Amber colored PET bottles

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-022	T-023	T-024
Batch Size	250 bottles	250 bottles	250 bottles
Manufacturing Date	Sep-2021	Sep-2021	Sep-2021

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate (Certificate# HFW-H (Drugs)56/98) issued by health 7 Family Welfare Department valid upto 18-02-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of License to import issued by AD I&E DRAP, Islamabad, has been submitted dated 22-12-2020 for import of 10.Kg of Loratadine.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Section#	Observations	Firm's response
3.2.S.4.4	COA of drug substance from M/s Caraway shall be submitted for the relevant batch used in formulation of drug product stability batches.	• COA submitted from M/s caraway for batch# LH10B-0708 of Loratadine.
3.2.S.5	COA of working standard with valid expiry date shall be submitted.	• COA of USP reference standard has been submitted.
3.2.P.8	• Microbiological reports shall be submitted for the performance of Microbial enumeration test. • Justification shall be submitted for not performing preservative efficacy test since applied formulation contains "Sodium benzoate" as preservative.	• Firm has submitted microbiological report for stability studies. • Firm has submitted preservative efficacy testing in the section of 3.2.P.2.5 of microbiological attributes.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit Pharmaceutical equivalence studies against the innovator/reference drug product before issuance of registration letter.**

1487.	Name, address of Applicant / Marketing Authorization Holder	M/s Seatle Private Limited, 45-KM Multan Road, Lahore.
	Name, address of Manufacturing site.	M/s Seatle Private Limited, 45-KM Multan Road, Lahore.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 17607 dated 16-06-2022
	Details of fee submitted	Rs.30,000/- dated 15-04-2022
	The proposed proprietary name / brand name	**Lexodow Tablet 3mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Bromazepam……..3mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Benzodiazepines
	Reference to Finished product specifications	As per Innovator's specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEXOTAN TABLET 3mg by Pharmaco Australia Ltd, TGA-Australia Approved.
	For generic drugs (me-too status)	Lexotanil Tablet by Martin Dow Limited (Reg No. 001043)
	GMP status of the Finished product manufacturer	GMP certificate issued on basis of inspection conducted on 23-12-2019
	Evidence of manufacturing facility	Tablet Psychotropic section granted on 27-09-2019.
	Name and address of API manufacturer.	CAMBREX Profarmaco Milano S.r.l. Via Curiel, 34 - 20067 Paullo, Milano – Italy
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of in APIMFs of both drug substances.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (700714, 730619, 760716)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Lexotanil tablet 3mg by Martin Dow Limited, Pakistan by performing quality tests (Identification, Disintegration, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Lexotanil tablet 3mg by Martin Dow Limited, Pakistan in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	CAMBREX Profarmaco Milano S.r.l. Via Curiel, 34 - 20067 Paullo, Milano – Italy		
API Lot No.	Bromazepam: 880110 (RM15001513)		
Description of Pack (Container closure system)	Alu-PVC blister of 1x10's packed in printed unit carton. (30's & 50's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	L-001-T	P-001-T	P-002-T
Batch Size	10,000 tablets	10,000 tablets	10,000 tablets
Manufacturing Date	24-12-2021	24-12-2021	24-12-2021
Date of Initiation	07-01-2022	07-01-2022	07-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate with valid till 01-2022 issued by AIFA Italy.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Bromazepam:** Firm has submitted copy of NOC (Ref. No. 19032 2020/DRAP/(AD-VIII) (I&E) dated 28-12-2020 for import of total 105g Bromazepam .
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
3.2.S.4.3	Analytical method verification studies have been performed for HPLC method whereas BP monograph mentions titration method for assay analysis.	For titration method, there is a requirement of a banned/controlled reagent of acetic anhydride for which we do not have authorization/stock at Seatle, so therefore an alternate method by HPLC was adapted for estimation of contents which is more stringent and specific and same has been validated & submitted with dossier application.
3.2.P.8.3	Copy of commercial invoice attested by AD I&E DRAP, shall be submitted for the import of Bromazepam batch# 880110 Justification shall be submitted for performance of Assay test by UV Spectrophotometric method.	Firm has submitted copy of commercial invoice no. 1000001874 attested by AD I&E DRAP Lahore dated 07-05-2021 stating that the NOC is for Bromazepam working standard only. As the product is not available in USP/BP/JP, an In-House method (By UV) for Bromazepam Tablets for assay was adopted and same has been validated & submitted with dossier. Moreover, specificity test was performed in validation studies, wherein it was found that there is no interference of blank (diluent) & placebo sample matrices with API (Bromazepam).

Decision: Deferred for submission of scientific justification for applying UV spectrophotometric method for drug product Assay test since drug substance assay has been performed by HPLC method.

1488.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceutical 19 km, Sheikhupura Road, Faisalabad.**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceutical 19 km, Sheikhupura Road, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on 03.01.2022
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 07.07.2020 which specifies Dry Powder Injectable (Cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 29326 dated 17-10-2022
	Details of fee submitted	Rs.30,000/- dated 05-10-2022
	The proposed proprietary name / brand name	**Sonnet 1g IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Each Vial Contains: Ceftriaxone Sodium equivalent to Ceftriaxone ……1000 mg
	Pharmaceutical form of applied drug	IM Injection

	Pharmacotherapeutic Group of (API)	Cephalosporin Antibacterial
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As Per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Rocephin Injection 1G IM of M/S F.Hoffmann-La Roche Ltd. Packed by Martin Dow Limited, Reg # 008436
	Name and address of API manufacturer.	M/s HENAN KANGDA PHARMACEUTICAL CO.,LTD.Block no.66 Jing wu Road, Xiang cheng City, Henan, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance(Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Rocephin Injection 1gm IM".
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA	
Manufacturer of APIs	M/S. Henan kangda pharmaceutical co.,ltd. Block no.66 Jing wu Road, Xiang cheng City, Henan, China.
API Lot No.	2022009013
Description of Pack	Glass vial

<table>
<tr><td colspan="2">(Container closure system)</td><td colspan="3"></td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30◦C ± 2◦C / 65% ± 5%RH
Accelerated: 40◦C ± 2◦C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>T-001</td><td>T-002</td><td>T-003</td></tr>
<tr><td colspan="2">Batch Size</td><td>300 Vials</td><td>300 Vials</td><td>300 Vials</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>29.04.2021</td><td>29.04.2021</td><td>29.04.2021</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>#</td><td>Documents To Be Provided</td><td colspan="3">Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of
the firm (if any)</td><td colspan="3">Firm has referred to their last inspection report for Elixa (Apixaban) 2.5mg & 5mg conducted on 08.10.2019, approved in 293rd meeting of Registration Board.

Following are details of few points;
• The HPLC software is 21CFR Compliant.
• Audit trail reports were available and physically checked by the inspection team.
• Firm has adequate monitoring and controls for stability chambers.
• Software is installed for continuous monitoring ofchambers.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Copy of GMP certificate (Certificate# HA20170010) issued by China Food & Drug Administration valid upto 16.02.2022</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested by AD I&E DRAP, Lahore has been submitted.
Ceftriaxone Sodium:
<table><tr><th>Batch No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>2022009013</td><td>3.5Kg</td><td>27.07.2020</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data pf stability batches along with batch manufacturing record and analytical record.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers
(real time and accelerated)</td><td colspan="3">Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
<tr><td colspan="5">Remarks of Evaluator:
Copy of valid GMP certificate/DML of the drug substance manufacturer shall be submitted issued by the relevant regulatory authority.
Firm has submitted valid copy of DML for the drug substance manufacturer issued by CFDA.</td></tr>
<tr><td colspan="5">Decision: Approved.
• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.
• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.</td></tr>
</table>

Case no. 03 Registration applications of import cases

a. New Cases (Human)

1489	**Name, address of Applicant / Importer**	**M/s Excel Medical Devices. Office No.3, 12th Floor, Jas Trade Centre Plot No. 39-A-1 Block 6, PECHS, Jamsh Town, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No:** 1774 **Address: Office No.3, 12th Floor, Jason Trade Centre Plot N 39-A-1 Block 6, Karachi** **Validity:** 22/08/2021 **Status:** by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-r Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwo gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	Republic of Korea
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized COPP (Certificate# 2019-D1-0007) issued by Ministry of Food & Drug Safety. • Free Sale status: The COPP endorses the free sale status of the applied product in Republic of Korea. • Firm has submitted Legalized copy of GMP certificate (Certificate No. 2018-D1-2931) issued by "Ministry Food & Drug Safety, in the name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansa si, Gyeonggi-do, Republic of Korea, issued on 31-08-2018.	
	Details of letter of authorization / sole agency agreement • Original Legalized "Letter of Authorization" issued by M/s Shin Poong Pharmaceutical Co., Ltd. 7, Won ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea in the name of M/s Excel Medical Devic Office No.3, 12th Floor, Jason Trade Centre Plot No. 39-A-1 Block 6, PECHS, Jamshed Town, Karac Pakistan for the applied product of "**Breta (letrozole) 2.5mg Tablet "**	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 26799 dated 12-10-2020
	Details of fee submitted	Rs. 100,000/-: 24-02-2020
	The proposed proprietary name / brand name	**Breta 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contain Letrozole ……. 2.5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Aromatase inhibitor ATC code: L02BG04
	Reference to Finished product specifications	In-House
	Proposed Pack size	30 tablets per pack
	Proposed unit price	PKR 7400/box.
	The status in reference regulatory authorities	Approved by MHRA of UK

	For generic drugs (me-too status)	Femara tablet of M/s Novartis (Reg.#021129)
	Module-II (Quality Overall Summary)	Submitted as per WHO-PD template
	Name, address of drug substance manufacturer	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwo gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Module-III Drug Substance:	The firm has submitted verification studies of assay method f API as well as for related substances.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Real time stability studies have been conducted at 25°C±2°C a 60%±5% RH for 36 months. Accelerated stability studies is conducted at 40°C±2°C and 75%±5% RH for 6 months.
	Module-III Drug Product:	All the relevant details are submitted by the firm.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The firm has comparative dissolution studies against the referen product Femara with acceptable values f2 values.
	Process Validation	Firm has submitted process validation studies of three batches f the applied product
	Analytical method validation/verification of product	Analytical method verification studies for drug product has n been submitted.
	Container closure system of the drug product	Pre-filled syringe: Barrel: Borosilicate glass Tip cap: Elastomer Plunger stopper: Bromobutyl rubber. Needle tube: Stainless steel 304
	Stability study data of drug product, shelf life and storage conditions	Real time stability studies have been conducted at 30°C±2°C a 65%±5% RH for 36 months. Accelerated stability studies is conducted at 40°C±2°C a 75%±5% RH for 6 months.

Evaluation by PEC[II]:

Section	Observation	Firm's response
2.3.P.2	Relevant information against this section shall be submitted**.**	Submitted.
3.2. S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer.	Firm has submitted analytical method verification report for drug product.

Decision: Approved as per policy of inspections of manufacturer abroad.

b. Deferred cases

1490.	**Name, address of Applicant / Importer**	**M/s Seatle Private Limited, 45-KM Multan Road, Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-351-0073-029396P **Address:** Seatle Private Limited, 45-KM Multan Road, Lahore. **Address of Godown:** NA **Validity:** 19-03-2022 (Renewal applied) **Status:** License to sell drugs in a Pharmacy **Renewal:** yes

	Name and address of marketing authorization holder (abroad)	LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona - Spain.
	Name, address of manufacturer(s)	**Drug product manufacturer:** LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain. **Water for injection 10ml:** Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France
	Name of exporting country	Spain
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 2020/01561) dated 20/06/2020 issued by Spanish Agency for Medicines and Health Products, Spain for Fratazid 1g powder and 10ml solvent for solution for injection (IV). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. Submitted COPP does not reflect any detail regarding manufacturer of the accompanying diluent i.e., 10ml WFI. **GMP:** Firm has submitted Legalized "Manufacturing authorization certificate no. 2279E" dated 26-11-2018, issued to LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain., wherein manufacturing facility for sterile products of B-lactam antibiotics" is confirmed. Firm has submitted Legalized "Manufacturing authorization certificate no. M 19/112" dated 13-06-2019, issued to Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France, wherein manufacturing facility for sterile products of Small Volume Parenteral" is confirmed. Copy of GMP certificate no. NCF/2024/001/CAT hs also been submitted for LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain valid upto 20-06-2020. Copy of Eudra GMP certificate no. 2020/HPF/FR/081 for Haut Pharma Livron

		SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France, valid upto 13-02-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted original legalized sole agency agreement. The agreement specifies that the manufacturer appoints M/s Seatle Private Ltd. to register their products in Pakistan as sole importer. A manufacturing agreement has also been submitted wherein M/s LDP-LABORATORIOS TORLAN, S.A. has declared Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France as manufacturer of the diluents i.e., Lidocaine HCl 1% ampoule & WFI ampoules for Ceftriaxone formulations to be imported by M/s Seatle.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 17398 dated 22-06-2021
	Details of fee submitted	For Ceftriaxone: PKR 100,000/-: 18-8-2020 For WFI: PKR 100,000/-: 15-06-2020
	The proposed proprietary name / brand name	**FRATAZID INJECTION 1g IV**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of powder contains: Ceftriaxone (as Sodium) …….. 1g Each Ampoule contains: Sterile Water for Injection ……10ml
	Pharmaceutical form of applied drug	Powder and solvent for solution for Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	Drug product: USP

		Diluent WFI: European Pharmacopoeia
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Rocephin Injection 1g **(USFDA** Approved).
	For generic drugs (me-too status)	Oxidil of SAMI Pharma Pvt. Ltd. (Reg # 022422)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Qilu Antibiotics Pharmaceutical Co., Ltd. No. 849 Dongjia Town, Licheng District, Jinan, Shandong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C and 60% RH The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence studies have been submitted against the Rocephin 1gm Injection.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

	Container closure system of the drug product	Type II glass vial for Powder Type I glass ampoule for WFI
	Stability study data of drug product, shelf life and storage conditions	**Drug product:** Firm has submitted stability study data of 3 batches of drug powder vial. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of all 3 batches is completed till 36 months. **Diluent WFI:** Firm has submitted stability study data of 3 batches of 10ml WFI. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of all 3 batches is completed till 60 months.
1491.	**Name, address of Applicant / Importer**	**M/s Seatle Private Limited, 45-KM, Multan Road, Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-351-0073-029396P **Address:** Seatle Private Limited, 45-KM, Multan Road, Lahore. **Address of Godown:** NA **Validity:** 19-03-2022 (Renewal applied) **Status:** License to sell drugs in a Pharmacy **Renewal:** Sale License is Valid
	Name and address of marketing authorization holder (abroad)	LDP-LABORATORIOS TORLAN S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona - Spain.
	Name, address of manufacturer(s)	**Drug product manufacturer:** LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain. **Lidocaine HCl 1%w/v:** Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France
	Name of exporting country	Spain
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 2020/01561) dated 20/06/2020 issued by Spanish Agency for Medicines and Health Products, Spain for Fratazid 1g powder and 10ml solvent for solution for injection (IV). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years.

		Submitted COPP does not reflect any detail regarding manufacturer of the accompanying diluent i.e., Lidocaine HCl 1% injection. **GMP:** Firm has submitted Legalized "Manufacturing authorization certificate no. 2279E" dated 26-11-2018, issued to LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain., wherein manufacturing facility for sterile products of B-lactam antibiotics" is confirmed. Firm has submitted Legalized "Manufacturing authorization certificate no. M 19/112" dated 13-06-2019, issued to Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France, wherein manufacturing facility for sterile products of Small Volume Parenteral" is confirmed. Copy of GMP certificate no. NCF/2024/001/CAT hs also been submitted for LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain valid upto 20-06-2020. Copy of Eudra GMP certificate no. 2020/HPF/FR/081 for Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France, valid upto 13-02-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted original sole agency agreement. The agreement specifies that the manufacturer appoints M/s Seatle Private Ltd. to register their products in Pakistan as sole importer.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only

	Dy. No. and date of submission	Dy. No 17396 dated 22-06-2021
	Details of fee submitted	For Ceftriaxone: PKR 100,000/-: 18-8-2020 For WFI: PKR 100,000/-: 15-06-2020
	The proposed proprietary name / brand name	**FRATAZID INJECTION 500g IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of powder contains: Ceftriaxone (as Sodium) …….... 500mg Each 2ml Ampoule contains: Sterile Lidocaine HCl ……20mg (Ph. Eur specification)
	Pharmaceutical form of applied drug	Powder and solvent for solution for Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	Drug product: USP Diluent Lidocaine HCl injection 2%w/v: European Pharmacopoeia
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Rocephin Injection 500mg **(USFDA** Approved).
	For generic drugs (me-too status)	Oxidil of SAMI Pharma Pvt. Ltd. (Reg # 022422)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	**Ceftriaxone:** Qilu Antibiotics Pharmaceutical Co., Ltd. No. 849 Dongjia Town, Licheng District, Jinan, Shandong Province, China. **Lidocaine:** Haupt Pharma Livron, 1 rue Comte de Sinard, Livron Sur Drome, 26250, France.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C ± 2°C and 60% RH the stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study has been submitted against Rocephin Injection 500mg.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type II glass vial for Powder Type I glass ampoule for Lidocaine
	Stability study data of drug product, shelf life and storage conditions	**Drug product:** Firm has submitted stability study data of 3 batches of drug powder vial. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of all 3 batches is completed till 36 months. **Diluent Lidocaine HCl 1%:** Firm has submitted stability study data of 3 batches. The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of all 3 batches is completed till 60 months.
1492.	**Name, address of Applicant / Importer**	**M/s Seatle Private Limited, 45-KM, Multan Road, Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-351-0073-029396P **Address:** Seatle Private Limited, 45-KM, Multan Road, Lahore. **Address of Godown:** NA **Validity:** 19-03-2022 (renewal applied) **Status:** License to sell drugs in a Pharmacy **Renewal:** Sale License is Valid
	Name and address of marketing authorization holder (abroad)	LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona - Spain.

	Name, address of manufacturer(s)	**Drug product manufacturer:** LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain. **Water for injection 5ml:** Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France
	Name of exporting country	Spain
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 2020/01568) dated 20/06/2020 issued by Spanish Agency for Medicines and Health Products, Spain for Fratazid 1g powder and 10ml solvent for solution for injection (IV). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. Submitted COPP does not reflect any detail regarding manufacturer of the accompanying diluent i.e., 10ml WFI. **GMP:** Firm has submitted Legalized "Manufacturing authorization certificate no. 2279E" dated 26-11-2018, issued to LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain., wherein manufacturing facility for sterile products of B-lactam antibiotics" is confirmed. Firm has submitted Legalized "Manufacturing authorization certificate no. M 19/112" dated 13-06-2019, issued to Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France, wherein manufacturing facility for sterile products of Small Volume Parenteral" is confirmed. Copy of GMP certificate no. NCF/2024/001/CAT hs also been submitted for LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain valid upto 20-06-2020. Copy of Eudra GMP certificate no. 2020/HPF/FR/081 for Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France, valid upto 13-02-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted original legalized sole agency agreement. The agreement specifies that

		the manufacturer appoints M/s Seatle Private Ltd. to register their products in Pakistan as sole importer. A manufacturing agreement has also been submitted wherein M/s LDP-LABORATORIOS TORLAN, S.A. has declared Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France as manufacturer of the diluents i.e., Lidocaine HCl 1% ampoule & WFI ampoules for Ceftriaxone formulations to be imported by M/s Seatle.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 17397 dated 22-06-2021
	Details of fee submitted	For Ceftriaxone: PKR 100,000/-: 18-8-2020 For WFI: PKR 100,000/-: 15-06-2020
	The proposed proprietary name / brand name	**Fratazid 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial of powder contains: Ceftriaxone (as Sodium) …….. 500mg Each Ampoule contains: Sterile Water for Injection ……5ml
	Pharmaceutical form of applied drug	Powder and solvent for solution for Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	European Pharmacopoeia
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Rocephin Injection 500mg **(USFDA** Approved).
	For generic drugs (me-too status)	Oxidil of SAMI Pharma Pvt. Ltd. (Reg # 022422)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Qilu Antibiotics Pharmaceutical Co., Ltd. No. 849 Dongjia Town, Licheng District, Jinan, Shandong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25ºC ± 2ºC and 60% RH The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence study has been submitted against Rocephin Injection 500mg IV
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type II glass vial for Powder Type I glass ampoule for WFI
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug powder vial and WFI ampoule. The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of all 3 batches is completed till 36 months.
Evaluation by PEC:		

Section#	Observations	Firm's response
1.3.4	Copy of valid Drug Sale License (DSL) issued by relevant licensing authority shall be submitted. Sole agency agreement / letter of authorization between applicant and marketing authorization holder shall be submitted.	Firm has submitted copy of DSL valid till 19-03-2022 along with receipt of renewal application. Copy of sole agency agreement from M/s LDP-Laboratorios TORLAN, S.A., Ctra Barcelona, Spain in the name of M.s Seatle Provate Ltd., Lahore, Pakistan has been submitted.
1.5.6	The said section declares Pharmacopoeial reference as European Pharmacopoeia specifications, monograph of applied product is not available in European Pharmacopoeia.	Firm has revise specifications to USP , without submission of fee.
2.3	Table for literature references for the drug substance & drug product has not been submitted.	Submitted.
2.3.P.5.1	Assay limits are not as per the Pharmacopoeial monograph.	Revised Specification and Analytical Procedure as per USP is submitted
2.3.R.1.1	Submitted BMR declare the calculation of drug substance fill weight per vial on the basis of "Assay of anhydrous active substance" instead of "Assay of as is active substance"	Firm has submitted revised BMRs.
3.2.S.4.2	• Copy of drug substance specifications and analytical procedure applied by Drug product manufacturer shall be submitted. • The USP monograph of Ceftriaxone sodium, recommends the potency of Ceftriaxone in USP Ceftriaxone Sodium RS (µg/mg) for the calculation of Assay, whereas submitted drug substance analytical procedure applies the potency of Ceftriaxone sodium in %age.	• Revised Specification and Analytical Procedure applied by Drug Product Manufacturer as per USP is submitted
3.2.S.4.3	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	• AMV report is submitted form Drug product manufacturer.
3.2.S.4.4	• The specifications for Assay test mentioned in the batch analysis certificate from drug product manufacturer are different from	• Revised COA, according to USP monograph and section 3.2.S.4.1 from Drug Product Manufacturer is submitted

	that submitted in section 3.2.S.4.1. • The drug substance COA from the M/s Qilu Pharma is as per USP monograph whereas COA from M/s LDP Laboratories Torlan S.A. is as per the BP monograph. Justification shall be submitted in this regard.	
3.2.P.2	• A brief information on the pharmaceutical development shall be included. This information specifies the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed. • Compatibility studies for the applied product shall be performed as per the instructions provided in individual label of the drug product.	• Submitted. • Compatibility study has been submitted for 1gm injection only with water for injection.
3.2. P.5.1	• Submitted drug product specifications does not include Assay limit for the content of dry powder injection i.e., an amount of Ceftriaxone Sodium equivalent to NLT 776 µg/mg of ceftriaxone • Test of crystallinity ha sot been included the drug product specifications.	• Revised Specifications according to USP including the test for crystallinity, are submitted.
3.2.P.5.2	• Sample preparation procedure mentioned in analytical method, does not include sample preparation for "Sample solution 2", as defined in the USP monograph of "Ceftriaxone for injection."	• Firm has submitted revised analytical procedure as per USP monograph
3.2.P.5.4	• Submitted COAs of drug product does not include Assay test for sample solution 2 as recommended by USP monograph of "Ceftriaxone for injection".	• Firm has submitted COA of recent batch of the drug product manufactured in May, 2022 wherein Assay analysis has been performed as per USP monograph.
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• Submitted.
3.2.P.8	• Submitted stability data does not reflect the performance of Assay test for sample solution 2 as	• Please note that the Sample Preparation Method mentioned in Analytical Method does not

	recommended by USP monograph of "Ceftriaxone for injection". • Data of stability batches shall be supported by respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	include sample preparation for "Sample Solution 2" and only the preparation of Sample Solution 1"is included. However, we will include both the preparation of Sample Solution 1 and Sample Solution 2 by revising the specifications and analytical procedures according to the USP Monograph. • Submitted.

Decision of 320th meeting: Registration Board deferred the applications of FRATAZID INJECTION 1g IV & FRATAZID INJECTION 500g IM for submission of CoPP with details of the composition and manufacturer of accompanying diluent.

Firm's response:
Firm has submitted revised original Legalized CoPPs of all three strengths issued by AEMPS Spain, detailed as below:

Product	**CoPP details**
Fratazid Injection 500mg IM	Firm has submitted original, legalized CoPP certificate (No. 2022/03010) dated 04-11-2022 issued by Spanish Agency for Medicines and Health Products, Spain for Fratazid 500mg powder and 2ml solvent for solution for injection (IM). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. Details of manufacturer as per COPP are as under: **Vials manufacturer:** LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain. **Solvent ampoules manufacturer:** Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France
Fratazid Injection 500mg IV	Firm has submitted original, legalized CoPP certificate (No. 2022/03009) dated 04-11-2022 issued by Spanish Agency for Medicines and Health Products, Spain for Fratazid 500mg powder and 5ml solvent for solution for injection (IV). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. Details of manufacturer as per COPP are as under: **Vials manufacturer:** LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain. **Solvent ampoules manufacturer:** Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France

	Fratazid Injection 1gm IV	Firm has submitted original, legalized CoPP certificate (No. 2022/03010) dated 04-11-2022 issued by Spanish Agency for Medicines and Health Products, Spain for Fratazid 500mg powder and 10ml solvent for solution for injection (IV). The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. Details of manufacturer as per COPP are as under: **Vials manufacturer:** LDP-LABORATORIOS TORLAN, S.A. Ctra. de Barcelona, 135-B 08290 Cerdanyola del Valles Barcelona – Spain. **Solvent ampoules manufacturer:** Haut Pharma Livron SAS, 1 rue Comte de sinard, 26250, Livron sur Drome. France
Decision: Registration Board approved the applications of Fratazid Injection 1g IV, Fratazid Injection 500g IM & Fratazid 500mg IV Injection with "Type I glass vial" as primary container, as per policy of inspections of manufacturer abroad.		

Case no. 04 Registration applications of priority consideration against manufacturing of Paracetamol tablets

1493.	Name and address of manufacturer / Applicant	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	**Fenomol 200mg/500mg Tablet**
	Composition	Each film coated tablet contains: Ibuprofen……. 200mg Paracetamol ……. 500mg
	Diary No. Date of R& I & fee	Dy. No. dated 09-02-2020, Fee Rs: 20,000/- dated 17-09-2014 vide deposit slip No.0143487. Fee Rs:30,000/- dated 08-07-2017 vide deposit slip No. 0275689.
	Pharmacological Group	Ibuprofen: NSAIDs Paracetamol: Antipyretic
	Type of Form	Form 5D
	Finished product Specifications	Tabros Specifications
	Pack size & Demanded Price	2x10's As per SRO
	Approval status of product in Reference Regulator Authorities	Nuromol Double Action Pain Relief 200mg/500mg Tablets (MHRA Approved)
	Me-too status	Provas Duo Tablets Sami Pharmaceuticals (Pvt). Ltd. Reg. No. 108579
	GMP status	GMP certificate issued based upon inspection conducted on 07-04-2022.
	Remarks of the Evaluator	
STABILITY STUDY DATA		

Manufacturer of API	**(Ibuprofen)** M/s Shandong Xinhua Pharmaceutical Co., Ltd. East Chemical Zone of Zibo High & New Technology Development Zone, Zibo, Shandong, P.R. China. **(Paracetamol)** M/s Hebei Jiheng Pharmaceutical Co., Ltd. No. 1 Wei wu Street Heng Shui Industrial Park He bei Province, China.		
API Lot No.	Ibuprofen: 2003785 Paracetamol: 012104147		
Description of Pack (Container closure system)	Alu-Alu blister pack.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TR001-1/FEN	TR002-1/FEN	TR003-1/FEN
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	Sep-2021	Sep-2021	Sep-2021
Date of Initiation	28-09-2021	28-09-2021	28-09-2021
No. of Batches	03		
Date of Submission	27-04-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
29.	Reference of previous approval of applications with stability study data of the firm	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board). • 2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
30.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	3. Copies of COAs (Batch#2003785) of API **(Ibuprofen)** from M/s Shandong Xinhua Pharmaceutical Co., Ltd. East Chemical Zone of Zibo High & New Technology Development Zone, Zibo, Shandong, P.R. China. And M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi. are submitted. 4. Copies of COAs (Batch# 012104147) of API **(Paracetamol)** from M/s Hebei Jiheng Pharmaceutical Co., Ltd. No. 1 Wei wu Street Heng Shui Industrial Park He bei Province, China. and M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi. Pakistan. are submitted.
31.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Methods used for analysis of APIs from both API Manufacturers and Finished Product Manufacturer are provided by the firm for Ibuprofen and Paracetamol.
32.	Stability study data of API from API manufacturer	Ibuprofen: Firm has submitted stability study data of API. Stability study is conducted at Real time

<table>
<tr><td></td><td></td><td>conditions; 30°C ± 2°C / 75% ± 5%RH for 24 months
Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months

<u>Paracetamol:</u> Firm has submitted stability study data of API as per zone IV-A. Stability study is conducted at Real time conditions; 30°C ± 2°C / 75% ± 5%RH for 24 months and at Accelerated conditions; 40°C ± 2°C / 75% ± 5%RH for 6 months.</td></tr>
<tr><td>33.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td><u>For Ibuprofen:</u> Firm has submitted copy of GMP certificate dated 02-08-2019 in the name of M/s Shandong Xinhua Pharmaceutical Co., Ltd.
East Chemical Zone of Zibo High & New Technology Development Zone, Zibo, Shandong, P.R. China. Valid till 01-08-2024.
<u>For Paracetamol:</u> The firm has submitted copy of Written Confirmation issued from Hebei Drug Administration, Peoples Republic of China for M/s Hebei Jiheng Pharmaceutical Co., Ltd. No. 1 Wei wu Street Heng Shui Industrial Park He bei Province, China. valid till 14.03.2024.</td></tr>
<tr><td>34.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td><u>For Ibuprofen</u>: The firm has submitted copy of ADC Attested invoice No. XH200900 dated 10-07-2020 from of M/s Shandong Xinhua Pharmaceutical Co., Ltd. No. 1 Lutai Road, High-tech District, Zibo, Shandong, P.R. China. for import of 2Kgs of Ibuprofen (Batch No 2003785) in name of M/s Tabros Pharma Pvt. Ltd. Essa House, 32-1-C, Block-6 PECHS, Karachi, attested by AD DRAP Karachi dated 30.07.2020
ADC signed Form 6 is attached while Form 3 and Form 7 are also available.

<u>For Paracetamol:</u> The firm has submitted copy of invoice No. Y0409 dated 21-04-2021 from Hebei Jiheng Pharmaceutical Co., Ltd. for import of 4.5Kg Paracetamol in the name of M/s Tabros Pharma Pvt. Ltd., Lahore attested by ADC DRAP, Karachi dated 19-05-2021.
ADC signed Form 6 is attached while Form 3 and Form 7 are also available.</td></tr>
<tr><td>35.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>36.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>37.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Frim has referred to excipients used by innovator.</td></tr>
<tr><td>38.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TR001-1/FEN</td><td>1500 tablets</td><td>09-2021</td></tr>
<tr><td>TR002-1/FEN</td><td>1500 tablets</td><td>09-2021</td></tr>
<tr><td>TR003-1/FEN</td><td>1500 tablets</td><td>09-2021</td></tr>
</table></td></tr>
</table>

39.	Record of comparative dissolution data (where applicable)	Provided CDP has been performed against the NUROMOL 200mg/500mg Tablet by Reckitt Benckiser Healthcare in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
40.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
41.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
42.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Sr.#	Observation	Firm's response
1.	Justification shall be submitted for the selection of dissolution parameters i.e., dissolution medium, apparatus, volume, rpm.	Initially, we have been reviewed the dissolution method of Ibuprofen Tablets in USP monograph, and followed the same parameters like, Volume, elapsed time and apparatus Type, apart from this dissolution medium and rpm was established by In-House method.
2.	Justification shall be submitted for the dissolution limits of NLT 80% (Q) in 60 minutes in phosphate buffer of pH 6.8 whereas the review literature of US FDA for another strength of same formulation i.e., "Advil Dual Action with Acetaminophen" of M/s Pfizer recommends following dissolution parameters and limits: "NLT Q in 15 minutes for both Ibuprofen and Acetaminophen in phosphate buffer of pH 7.2."	The implemented dissolution method reviewed and found acceptable based on comparative dissolution profile at 6.8pH Buffer, we obtained Dissolution results in 6.8pH buffer (QC Medium) of Ibuprofen and Paracetamol more than 80% at 15 minutes, However, we have the yard stick USP compendia for Ibuprofen, where sample elapsed time is 60 minutes, Therefore, we kept sample Elapsed time is 60 minutes similar to USP compendia. Since, Competent Authority compared the dissolution with our product to Advil Dual action tablets as a reference product where the limit is NL T Qin 15 minutes, subsequently, we have noticed that Advil Dual action tablets excipients are entirely different as per our suggested reference product of NUROMOL. (Reckitt Benckiser Healthcare UK)

Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.

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

Case no. 05 Priority as per Authority Decision of 129th meeting for Invalid Registration

1494.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Libra Pvt aLtd. 77-Peshawar Industrial Estate, Hayatabad Peshawar**
	Name, address of Manufacturing site.	M/s Libra Pvt Ltd. 77-Peshawar Industrial Estate, Hayatabad Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	GMP certificate issued on basis of inspection conducted on 18-11-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 28-09-2004, declaring grant following additional sections: "Dry powder suspension (Cephalosporin)"
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 22874 dated 12-08-2022
	Details of fee submitted	Rs.30,000/- dated 07-01-2022
	The proposed proprietary name / brand name	**Libroxime DS 200mg/5ml Dry Powder for Oral Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cefixime as Trihydrate …… 200mg
	Pharmaceutical form of applied drug	Dry suspension oral
	Pharmacotherapeutic Group of (API)	Third-Generation Cephalosporin's
	Reference to Finished product specifications	USP specification
	Proposed Pack size	1's x 30ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Cefspan DS dry suspension of M/s Barret Hodgson Karachi (Reg.#024634)
	Name and address of API manufacturer.	M/s Pharmagen Ltd., Ferozpur Road, Lahore
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Cefspan DS dry suspension of M/s Barret Hodgson Karachi" has been submitted.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long-term conditions.

STABILITY STUDY DATA

Manufacturer of APIs	M/s Pharmagen Ltd., Ferozpur Road, Lahore		
API Lot No.	00243/128/2019		
Description of Pack (Container closure system)	Amber glass vial		
Stability Storage Condition	Real time: 25°C ± 2°C / 60% ± 5%RH Accelerated:		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	1000 bottles	1000 bottles	1000 bottles
Manufacturing Date	11-2019	11-2019	11-2019

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	**Documents To Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP certificate issued on basis of inspection conducted on 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Section	**Observation**	**Firm's response**
3.2. S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical	

	Ingredient by both Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer fshall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.		
3.2. S.7	• Clarification shall be submitted whether provided stability studies of drug substance is for "Compacted" form or "Micronized form".		
3.2. P.2.1	Details of accompanying reconstitution diluent shall be submitted.		
3.2.P.2.2.1	The said section declares the usage as "Anti-ulcer". Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.		
3.2.P.2.5	• Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia shall be provided		
3.2.P.2.6	• Compatibility study with re constitution diluent shall be submitted.		
3.2. P.5.1	• Submitted drug product test method does not include details of chromatographic conditions for Assay test. • Test for content of antimicrobial preservative & efficacy of preservative, as recommended by ICH Q1 (R2) guidelines & USP chapter <51>, has not been included in the finished product specifications. You are advised to submit justification in this regard.		
3.2. P.8	• Long term conditions mentioned on stability summary sheets are not as per Zone IV. • Complete data of stability batches shall be provided including chromatograms, Raw data sheets, COA, summary data sheets etc. for both accelerated and long term stability conditions. • Temperature & Humidity record for stability chambers shall be submitted.		

	• Complete batch manufacturing record for stability batches shall be submitted. • In-use stability data shall be submitted. • Documents for the procurement of API.		
Decision: Deferred for submission of reply of above cited shortcomings within six months.			

Case no. 06 Registration applications on Form 5 (Human)

a. New Cases

1495	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Lotan 50mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium … 50mg
	Diary No. Date of R& I & fee	Dy.No 13534 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Angiotensin II antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bepsar 50mg Tablet by M/s Nabiqasim Karachi.
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator II:	
	Decision: Approved.	
1496	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	Lotan 100mg film coated Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium … 100mg
	Diary No. Date of R& I & fee	Dy.No 13528 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Angiotensin II antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bepsar 100mg Tablet by M/s Nabiqasim Karachi.
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator II:	
	Decision: Approved.	
1497	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	URIOFF 40mg Film coated Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat ….. 40mg
	Diary No. Date of R& I & fee	Dy.No 13543 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Anti-Gout
	Type of Form	Form 5

	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Febuxin by M/s AGP, Karachi
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1498	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	URIOFF 80mg Film coated Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat ….. 80mg
	Diary No. Date of R& I & fee	Dy.No 13542 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Anti-Gout
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Febuxin by M/s AGP, Karachi
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1499	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	IBTAN 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan …… 300mg
	Diary No. Date of R& I & fee	Dy. No 13540 dated 07-03-2019 Rs.20,000 dated 06-03-2019
	Pharmacological Group	Angiotensin II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Arbi 300mg Tablet of M/s Pharmevo Karachi (Reg.# 073770)
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator II:	
	Decision:	
1500	**Name and address of manufacturer / Applicant**	**M/s Maxitech Pharma Pvt Ltd. Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi**
	Brand Name + Dosage Form + Strength	IBTAN 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Irbesartan …… 75mg
	Diary No. Date of R& I & fee	Dy.No 13538 dated 07-03-2019 Rs.20,000/- dated 06-03-2019

	Pharmacological Group	Angiotensin II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifcations
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Arbi Tablet of M/s Pharmevo Karachi
	GMP status	GMP certificate issued on 31.08.2022
	Remarks of Evaluator [II]:	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1501	**Name and address of manufacturer / Applicant**	**M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad**
	Brand Name + Dosage Form + Strength	Desler 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine …... 5mg
	Diary No. Date of R& I & fee	Dy.No 16929 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Desdine 5mg Tablet of M/s M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080821)
	GMP status	The firm have submitted cGMP certificate issued on 22-03-2019 based on inspection conducted on 01-03-2019
	Remarks of Evaluator [II]: Latest GMP inspection report conducted within last three years shall be submitted.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1502	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Hifexo 180mg Tablet
	Composition	"Each Film Coated Tablet Contains: Fexofenadine HCl…..…180mg"
	Diary No. Date of R& I & fee	Dy.No 13509 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihistamines
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FEXOTABS 180mg film coated tablet, TGA Approved
	Me-too status (with strength and dosage form)	Axofed 180mg Tablet by M/s Akson Pharmaceuticals, (Reg# 101790)
	GMP status	
	Remarks of the Evaluator [II]: Submit latest GMP inspection report conducted within last three years.	
	Decision: Approved with USP specifications. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	

1503	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Linzosun 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…400mg
	Diary No. Date of R& I & fee	Dy.No 13501 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZYVOX 400mg film-coated tablets Tablet USFDA Approved. Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons*
	Me-too status (with strength and dosage form)	Zvox 400mg Tablet by M/s Arreta Pharmaceuticals (Reg# 084279)
	GMP status	
	Remarks of the Evaluator II: Submit latest GMP inspection report conducted within last three years.	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1504	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Montisun 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Montelukast Sodium…10mg
	Diary No. Date of R& I & fee	Dy.No 13506 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved.
	Me-too status (with strength and dosage form)	Montiget 10mg tablet Reg. No. 034838 M/s Getz Pharmaceuticals.
	GMP status	
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring the label claim for Montelukast sodium in terms of Montelukast base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. Submit latest GMP inspection report conducted within last three years.	
	Decision: Approved with USP specifications. The firm shall submit revised label claim as per innovator product declaring the label claim for Montelukast sodium in terms of Montelukast base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 as well as latest GMP inspection report conducted within last three years before issuance of registration letter.	
1505	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Omesun 40/1100 mg Capsule
	Composition	Each Capsule Contains: Omeprazole …… 40mg Sodium Bicarbonate ……. 1100mg

	Diary No. Date of R& I & fee	Dy. No 13511 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZEGERID® (40 mg Omeprazole and 1,100 mg Sodium bicarbonate) capsules (USFDA Approved)
	Me-too status (with strength and dosage form)	Ozimed Capsule 40/1100mg of M/s Welmed pharmaceuticals, Swabi. Registration No. 102786
	GMP status	
	Remarks of the Evaluator II: Submit latest GMP inspection report conducted within last three years.	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1506	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Xeotane 20mg Capsule
	Composition	Each Capsule Contains: Isotretinoin…20mg
	Diary No. Date of R& I & fee	Dy.No 13502 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Retinoids
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Acnewin Capsule 20mg of Wnsfield Pharmaceuticals (Reg.# 064335)
	GMP status	
	Remarks of the Evaluator II: • Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility. • In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.	
	Decision: Deferred for following: **• Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility.** **• In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.**	
1507	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Xeotane 10mg Capsule
	Composition	Each Capsule Contains: Isotretinoin…10mg
	Diary No. Date of R& I & fee	Dy.No 13504 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Retinoids
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA

	Me-too status (with strength and dosage form)	Acnewin Capsule 10mg of Wnsfield Pharmaceuticals
	GMP status	
	Remarks of the Evaluator [II]: • Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility. • In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.	
	Decision: Deferred for following: **• Clarification shall be submitted whether applied formulation is hard gelatin capsule or soft gelatin capsule, along with evidence of required of manufacturing facility.** **• In case the applied formulation is hard gelatin capsule, submit stability studies as per decision of 250th meeting of Registration Board according to guidelines of approve din 293rd meeting of Registration Board.**	
1508	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Linzosun 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy.No 13500 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved.
	Me-too status (with strength and dosage form)	Zvox 600mg Tablet by M/s Arreta Pharmaceuticals
	GMP status	
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1509	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Isoderm Gel
	Composition	Each Gram Contains: Isotretinoin…0.5mg
	Diary No. Date of R& I & fee	Dy.No 13503 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Retinoid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Isotrex gel 0.05% w/w. MHRA Approved
	Me-too status (with strength and dosage form)	Iso-Scot Gel 0.05%. Reg # 37706
	GMP status	
	Remarks of the Evaluator [II]: Firm has approval of Cream/Ointment section vide Letter No. F. 3-8/2004-Lic. Dated 12-09-2007.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-	

	05-2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1510	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Xeotraxin E Gel
	Composition	Each Gm Contains: Isotretinoin…0.5mg Erythromycin…20mg
	Diary No. Date of R& I & fee	Dy.No 13505 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Retinoid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Vegatrex Gel by M/s Vega Pharmaceuticals (Reg#83841)
	GMP status	
	Remarks of the Evaluator II: Firm has approval of Cream/Ointment section vide Letter No. F. 3-8/2004-Lic. Dated 12-09-2007. Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1511	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Solisun 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…….5mg
	Diary No. Date of R& I & fee	Dy.No 13516 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Natrilam tablets 5mg of M/s Serveir Research & Pharmaceuticals Pakistan (Reg.# 090507)
	GMP status	
	Remarks of the Evaluator II:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1512	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Sitamet 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate……50mg Metformin HCl…….500mg
	Diary No. Date of R& I & fee	Dy.No 13516 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti diabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (with strength and dosage form)	Treviamet Tablet of M/s Getz Pharma Karachi.
	GMP status	
	Remarks of the Evaluator [II]: Submit revised label claim as per innovator product declaring the label claim for Sitagliptin phosphate monohydrate in terms of Sitagliptin base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved with Innovator's specifications. The firm shall submit revised label claim as per innovator product declaring the label claim for Sitagliptin phosphate monohydrate in terms of Sitagliptin base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
1513	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Lornosun 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…….8mg
	Diary No. Date of R& I & fee	Dy.No 13518 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-inflammatory and Antirheumatic Products
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Xefo 8mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
	Me-too status (with strength and dosage form)	Acabel Tablets 8mg, S.J & G Fazul Ellahie, Reg. No. 061604.
	GMP status	
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
1514	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Tamsoun 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulosin HCl…0.4mg
	Diary No. Date of R& I & fee	Dy. No 13515 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Alpha 1 adrenergic receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Uripro 0.4mg Capsule M/s Getz Pharma (Reg.#081040)
	GMP status	
	Remarks of the Evaluator [II]: Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva.	
	Decision: Approved. Firm shall submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-IVa along with latest GMP inspection report conducted within last three years.	

1515	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Amlo-V 5/80 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine……5mg Valsartan…….80mg"
	Diary No. Date of R& I & fee	Dy.No 13508 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Exforge Tablet by Novartis
	GMP status	
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring the complete salt form of Amlodipine, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approve. The firm shall submit revised label claim as per innovator product declaring the complete salt form of Amlodipine, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1516	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Amlo-V 5/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine……5mg Valsartan…….160mg"
	Diary No. Date of R& I & fee	Dy.No 13510 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Exforge Tablet by Novartis
	GMP status	
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring the complete salt form of Amlodipine, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approve. The firm shall submit revised label claim as per innovator product declaring the complete salt form of Amlodipine, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1517	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Rovasun 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium…10mg
	Diary No. Date of R& I & fee	Dy.No 13512 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5

	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Xplendid Tablets by M/s Pharmevo
	GMP status	
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring the label claim in terms of Rosuvastatin base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. Firm has claimed manufacturer specifications, whereas pharmacopoeial monograph is available for applied formulation.	
	Decision: Approve with USP specifications. The firm shall submit revised label claim as per innovator product declaring the label claim in terms of Rosuvastatin base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1518	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Rovasun 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium…20mg
	Diary No. Date of R& I & fee	Dy.No 13512 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Xplendid Tablets by M/s Pharmevo
	GMP status	
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring the label claim in terms of Rosuvastatin base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021. Firm has claimed manufacturer specifications, whereas pharmacopoeial monograph is available for applied formulation.	
	Decision: Approve with USP specifications. The firm shall submit revised label claim as per innovator product declaring the label claim in terms of Rosuvastatin base, along with master formulation and fee of Rs. 30,000/- as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1519	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Itosun 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride HCl…150mg
	Diary No. Date of R& I & fee	Dy.No 13520 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Gastroprokinetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--

	Me-too status (with strength and dosage form)	Itoride tablet of amarant pharma
	GMP status	
	Remarks of the Evaluator II: Submit evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1520	**Name and address of manufacturer / Applicant**	**M/s Hisun Pharmaceutical Industries. Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan**
	Brand Name + Dosage Form + Strength	Gabisun 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy.No 13519 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-epileptics
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 50mg Capsule by M/s Getz Pharma
	GMP status	
	Remarks of the Evaluator II: Firm has claimed manufacturer specifications, whereas pharmacopoeial monograph is available for applied formulation.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 alongwith latest GMP inspection report conducted within last three years before issuance of registration letter.	
1521	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Caldolar Injection 100mg/ml
	Composition	Each Ampoule Contains: Ibuprofen…100m
	Diary No. Date of R& I & fee	Dy.No 15058 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA Australia
	Me-too status (with strength and dosage form)	Xaleve injection of M/s Hudson pharma Karachi(Reg.# 093088)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator II: Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board.	
	Decision: Registration Board deferred the case for submission of stability studies data as per checklist within 6 months.	
1522	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Colchi 4mg Injection
	Composition	Each 2ml Contains: Thiocolchicoside …. 4mg
	Diary No. Date of R& I & fee	Dy .No 15055 dated 07-03-2019 Rs.20,000 dated 07-03-2019

	Pharmacological Group	Skeletal Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved
	Me-too status (with strength and dosage form)	Myolax Injection of M/s Reko Pharmaceuticals, Lahore 069277
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1523	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Cosamide 200mg Injection
	Composition	Each 20ml Vial Contains: Lacosamide … 200mg
	Diary No. Date of R& I & fee	Dy. No 15054 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved
	Me-too status (with strength and dosage form)	VIMPAT Lacosamide 200 mg/20 mL injection 20 ml vial. TGA approved
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]: As per submitted GMP certificate firm has "Liquid Injectable (Ampoule & Vial) section."	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1524	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	D 3 Injection 5mg/ml
	Composition	Each Ampoule Contains: Cholecalciferol (Vitamin D3)…..…5mg
	Diary No. Date of R& I & fee	Dy. No 16189 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Vitamin D3 analogue
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]:	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	

1525	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	GT-Zole 100mg Injection
	Composition	Each 50ml Contains: Fluconazole … 100mg
	Diary No. Date of R& I & fee	Dy.No 15053 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	--
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator II: Submit evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1526	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Lincons 300 Injection
	Composition	Each 1ml Ampoule Contains: Lincomycin as HCl…300mg
	Diary No. Date of R& I & fee	Dy.No 15052 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lincocin Injection 300mg of M/s Pfizer Japan Inc." approved by PMDA of Japan
	Me-too status (with strength and dosage form)	Lincofac 300mg/1ml Injection of m/s Unitech (Reg.#039658)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator II: USP monograph is available for applied formulation.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1527	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Lincons 600 Injection
	Composition	Each 2ml Ampoule Contains: Lincomycin as HCl …. 600mg
	Diary No. Date of R& I & fee	Dy.No 15051 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lincocin 600mg/2ml injection by M/s Pfizer, USFDA Approved.
	Me-too status (with strength and dosage form)	Leemed 600mg Injection by M/s Medley Pharmaceuticals Wah Cantt. Reg. No. 79210

	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]: USP monograph is available for applied formulation.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1528	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Mont Sachet 4mg
	Composition	Each Sachet Contains: Montelukast Sodium…4mg
	Diary No. Date of R& I & fee	Dy.No 16188 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Leukotriene antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, as per SRO
	Approval status of product in Reference Regulatory Authorities	Montelukast Sodium 4 mg Oral Granules by M/s Highnoon Laboratories, MHRA Approved.
	Me-too status (with strength and dosage form)	Aerotel Sachet of M/s Highnoon Laboratories. (Reg.#044768)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]: Submit revised label claim as per innovator product declaring the strength in terms of base form of Montelukast, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved. Firm shall submit revised label claim as per innovator product declaring the strength in terms of base form of Montelukast, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021 before issuance of registration letter.	
1529	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Renitix 50 Injection
	Composition	Each Ampoule Contains: Ranitidine As HCl … 50mg / 2ml
	Diary No. Date of R& I & fee	Dy.No 15049 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10ml x 2ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ranitidine 50mg/2ml Solution (ampoule) for Injection and Infusion (**MHRA** Approved)
	Me-too status (with strength and dosage form)	Ranigen 50mg/2ml Injection by Genix Pharma (Reg# 083773)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]: Registration Board in its 294th meeting has decided to suspend registration of all ranitidine containing medicinal products, based upon the FDA decision.	
	Decision: Deferred till the decision of ranitidine containing formulations by reference regulatory authoirites.	
1530	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Simulta 0.4mg Capsule
	Composition	"Each Capsule Contains: Tamsulosin HCl…0.4mg"

	Diary No. Date of R& I & fee	Dy.No 15408 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Alpha 1 adrenergic receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Uripro 0.4mg Capsule M/s Getz Pharma (Reg.#081040)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]: Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-IVa.	
	Decision: Approved. Firm shall submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva.	
1531	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Toazole 100mg Capsule
	Composition	Each Capsule Contains: Itraconazole …. 100mg
	Diary No. Date of R& I & fee	Dy.No 15408 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-fungal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mukil Capsule 100mg of M/s. Dyson Research Laboratories (Pvt) Ltd (Reg.# 055356)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]: Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-IVa.	
	Decision: Approved. Firm shall submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva.	
1532	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	XEMTRAN 250 Injection
	Composition	Each Ampoule Contains: Tranexamic Acid …… 250mg / 5ml
	Diary No. Date of R& I & fee	Dy.No 15057 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Anti-Fibrinolytic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per S.R.O.
	Approval status of product in Reference Regulatory Authorities	Transcermin Note 5 % Injection by M/S Daiichi Sankyo Co., Ltd. (PMDA Japan Approved)
	Me-too status (with strength and dosage form)	Dravix 250mg/5ml injection of Getz pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator [II]: BP monograph is available for applied formulation.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	

1533	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Xemtran 500 Injection
	Composition	Each Ampoule Contains: Tranexamic Acid…500mg
	Diary No. Date of R& I & fee	Dy.No 15057 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRANEXAMIC ACID IV APOTEX tranexamic acid 500 mg/5 mL solution for injection vial. TGA approved
	Me-too status (with strength and dosage form)	Enxamin Injection 500mg. Reg. No. 52925
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator II: BP monograph is available for applied formulation.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1534	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	XI-CAMP 10mg Capsule
	Composition	Each Capsule Contains: Piroxicam …. 10mg
	Diary No. Date of R& I & fee	Dy.No 15045 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FELDENE 20mg CAPSULES by M/s Pfizer Limited. MHRA approved
	Me-too status (with strength and dosage form)	FELDEN 20MG CAP by Pfizer Karachi. (Reg#006349)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator II:	
	Decision: Approved.	
1535	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Xilcin 300mg Capsule
	Composition	Each Capsule Contains: Clindamycin as HCl … 300mg
	Diary No. Date of R& I & fee	Dy.No 15043 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Clindacure Capsule of M/s Hiranis (Reg.#076494)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.

	Remarks of the Evaluator II: Reference for drug product specifications shall be submitted.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1536	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Xilcin 150mg Capsule
	Composition	Each Capsule Contains: Clindamycin as HCl … 150mg
	Diary No. Date of R& I & fee	Dy.No 15044 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Clindac Capsule of M/s MKB Pharmaceuticals (Reg.#050977)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator II: Reference for drug product specifications shall be submitted.	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1537	**Name and address of manufacturer / Applicant**	**M/s GT Pharma Pvt Ltd. 23km, Raiwind Road, Lahore**
	Brand Name + Dosage Form + Strength	Xolon 10mg Injectionv
	Composition	Each 2ml Ampoule Contains: Metochloproamide HCl … 10mg / 2ml
	Diary No. Date of R& I & fee	Dy.No 15042 dated 07-03-2019 Rs.20,000 dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by US FDA
	Me-too status (with strength and dosage form)	Vominor injection of M/s Nortech Pharmaceuticals (Reg.#080000)
	GMP status	GMP certificate issued on basis of inspection conducted on 13-10-2021.
	Remarks of the Evaluator II: Submit revised label claim as per innovator product declaring the strength in terms of base form of Metoclopramide, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
	Decision: Approved. Firm shall submit revised label claim as per innovator product declaring the strength in terms of base form of Metoclopramide, along with master formulation and relevant fee as per Notification No. F.7-11/2012-B&A/DRAP dated 07th May, 2021.	
1538	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Tech 20mg Capsule
	Composition	Each Capsule Contains: Duloxetine as HCl …20mg
	Diary No. Date of R& I & fee	Dy.No 17206 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dulan capsules of M/s Hilton Pharma (Pvt.) Limited Karachi (Reg.# 055447)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator II: Submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-IVa.	
	Decision: Approved. Firm shall submit source of pellets along with relevant documents. i.e., COA, GMP certificate of supplier and stability studies data of the pellets as per Zone-Iva.	
1539	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Befart 80/480 mg Tablet
	Composition	Each Tablet Contains: Artemether…80mg Lumefantrine…480mg
	Diary No. Date of R& I & fee	Dy.No 17188 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status (with strength and dosage form)	Artem -DS Plus Tablets 80/480 of M/s Hilton Pharma, Karachi (Reg.# 066843)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator II:	
	Decision: Approved.	
1540	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Acnac 100mg Tablet
	Composition	Each Tablet Contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Dy.No 17197 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Rheumatoid arthritis
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Aclofen Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg.# 068419)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator II:	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1541	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**

	Brand Name + Dosage Form + Strength	Acodol 0.5mcg Tablet
	Composition	Each Tablet Contains: Alfacalcidol…0.5mcg
	Diary No. Date of R& I & fee	Dy.No 17202 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished product Specifications	Manufacturer Specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	one alpha tablet 0.5µg by Teijin Pharma Corporation PMDA Japan approved
	Me-too status (with strength and dosage form)	Alfasta Tablet 0.5mcg by M/s Star Labs, Reg. No. 81397
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]:	
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1542	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Cipex 250mg/5ml Suspension
	Composition	Each 5ml Contains: Ciprofloxacin…250mg
	Diary No. Date of R& I & fee	Dy.No 17198 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Quash suspension of M/s Wilshire Laboratories Pvt. Ltd.
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: Submit details for source of drug substance pellets along with, COA, GMP certificate and stability studies. Details of the accompanying diluent for reconstitution shall be submitted along with the manufacturing area in which it will be produced	
	Decision: Approved with diluent as per innovator drug product. Firm shall submit details for source of drug substance pellets along with, COA, GMP certificate and stability studies.	
1543	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Cyco 1000mcg 2ml Injection
	Composition	Each Injection Contains: Vitamin B12…1000mcg
	Diary No. Date of R& I & fee	Dy.No 17191 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	--

	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: • Evidence of applied formulation/drug already approved by DRAP (generic / me too status) alongwith registration number, brand name & name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me too status) alongwith registration number, brand name & name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
1544	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Cyco 500mcg 2ml Injection
	Composition	Each Injection Contains: Vitamin B12…500mcg
	Diary No. Date of R& I & fee	Dy.No 17189 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	Adcyna Injection (500mcg/2ml). Reg. No. 78924
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1545	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Esitech 20mg Tablet
	Composition	Each Tablet Contains: Escitalopram…20mg
	Diary No. Date of R& I & fee	Dy.No 17186 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Zavesca tablet 20mg of Getz Pharma. (Reg.#045281)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: • Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	

	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1546	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Kaytine 25mg CR Tablet
	Composition	Each Tablet Contains: Paroxetine.…25mg
	Diary No. Date of R& I & fee	Dy.No 17203 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil CR Tablet **(USFDA** Approved)
	Me-too status (with strength and dosage form)	Paraxyl Tablet by CCL Pharmaceuticals
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator II: Submit revised label as per innovator product declaring dosage form as film coated enteric coated controlled release tablet and salt form of paroxetine along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated enteric coated controlled release tablet and salt form of paroxetine along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1547	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Lamide 50mg Tablet
	Composition	Each Tablet Contains: Lacosamide …… 50mg
	Diary No. Date of R& I & fee	Dy.No 17257 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiepiletic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat 50mg tablet of M/s UCB INC Pharmaceuticals, (USFDA Approved)
	Me-too status (with strength and dosage form)	Lalap 50mg tablet of M/s Genix Pharma (Reg. # 070458)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator II: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved with Innovator's specifications. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1548	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Lamide 50mg Tablet
	Composition	Each Tablet Contains: Lacosamide…50mg
	Diary No. Date of R& I & fee	Dy.No 17257 dated 07-03-2019 Rs.20,000/- dated 07-03-2019

	Pharmacological Group	Antiepiletic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat 50mg tablet of M/s UCB INC Pharmaceuticals, (USFDA Approved)
	Me-too status (with strength and dosage form)	Lalap 50mg tablet of M/s Genix Pharma (Reg. # 070458)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved with Innovator's specifications. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1549	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Pyne 10/160 mg Tablet
	Composition	Each Tablet Contains: Amlodipine as besylate……10mg Valsartan……..160mg
	Diary No. Date of R& I & fee	Dy.No 17204 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Exforge by M/s Novartis
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1550	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Pyne 5/80 mg Tablet
	Composition	Each Tablet Contains: Amlodipine as besylate …… 5mg Valsartan …….. 80mg
	Diary No. Date of R& I & fee	Dy.No 17205 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Exforge by M/s Novartis

	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1551	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Repdon 2mg Tablet
	Composition	Each Tablet Contains: Resperidone…2mg
	Diary No. Date of R& I & fee	Dy.No 17183 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Riss 2mg Tablet of M/s Shawan Pharmaceuticals, Islamabad
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: Submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1552	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Tadol 100mg SR Capsule
	Composition	Each Capsule Contains: Tramadol……100mg
	Diary No. Date of R& I & fee	Dy.No 17201 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Opiate analogue
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Conzip capsules approved by USFDA as Extended release capsules
	Me-too status (with strength and dosage form)	Zultra SR 100mg by M/s. Wilshire Laboratories (Pvt.) Ltd; (Reg#080714)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator [II]: Innovator product capsules contain a total dose of tramadol hydrochloride 100, 200, and 300 mg in a combination of immediate-release and extended-release components, whereas no such declaration has been submitted by firm.	
	Decision: Deferred for justification of applied formulation against the innovator drug product as Innovator drug product capsules contain a total dose of tramadol hydrochloride 100, 200, and 300 mg in a combination of immediate-release and extended-release components, whereas no such declaration has been submitted by firm.	
1553	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**

	Brand Name + Dosage Form + Strength	Tadol 50mg Capsule
	Composition	Each Capsule Contains: Tramadol…50mg
	Diary No. Date of R& I & fee	Dy.No 17183 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Opiate analogue
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol 50mg capsule by Milpharm Ltd, approved by MHRA of UK.
	Me-too status (with strength and dosage form)	Tramal capsule 50mg by Impex Plus Karachi (Reg#010170)
	GMP status	GMP certificate issued on basis of inspection conducted on 30-01-2020
	Remarks of the Evaluator II:	
	Decision: Approved.	
1554	**Name and address of manufacturer / Applicant**	**M/s Karachi Chemical Industries pvt Ltd F/25, Estate Avenue, S.I.T.E Karachi**
	Brand Name + Dosage Form + Strength	Kaytine 12.5mg CR Tablet
	Composition	Each Tablet Contains: Paroxetine…12.5mg
	Diary No. Date of R& I & fee	Dy.No 17199 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Paxil CR Tablet **(USFDA** Approved)
	Me-too status (with strength and dosage form)	Paraxyl Tablet by CCL Pharmaceuticals
	GMP status	
	Remarks of the Evaluator II: Submit revised label as per innovator product declaring dosage form as film coated enteric coated controlled release tablet and salt form of paroxetine along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021	
	Decision: Approved. Firm shall submit revised label as per innovator product declaring dosage form as film coated enteric coated controlled release tablet and salt form of paroxetine along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.	
1555	**Name and address of manufacturer / Applicant**	**"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Oxyl-P 10/10mg delayed release tablet
	Composition	"Each film coated tablet contains: Doxylamine succinate …… 10mg Pyridoxine HCl …… 10mg"
	Diary No. Date of R& I & fee	Dy. No 18305 dated 18-05-2018, Rs. 20,000/- dated 17-05-2018
	Pharmacological Group	Antihistamine/Vitamin B6
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclegis tablet approved by US FDA
	Me-too status (with strength and dosage form)	Xyquil DR tablet of M/s Sami Pharmaceuticals (076469)
	GMP status	28-05-2022 Satisfactory level of GMP compliance.

	Remarks of the Evaluator[II]	Firm has applied for film coated dosage form, whereas innovator product is approved as delayed release tablet. Submitted master formulation does not contain any ingredient for delayed release profile. Firm has claimed USP specifications whereas no USP monograph is available for applied formulation. Frim shall submit revised master formulation as per innovator product declaring the dosage form as "delayed release tablet along with submission of fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021 • Firm has submitted revised formulation for delayed release tablet along with fee of Rs. 30,000/-- vide deposit slip#04220711. Revised label claim is as under; ""Each delayed release tablet contains: Doxylamine succinate …… 10mg Pyridoxine HCl …… 10mg"
	Decision: Approved as per following label claim: **"Each delayed release tablet contains:** **Doxylamine succinate …… 10mg** **Pyridoxine HCl …… 10mg"**	
1556	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt) Ltd, Plot # 129, sunder estate, Raiwind road Lahore
	Brand Name +Dosage Form + Strength	**Ferrowim injection**
	Diary No. Date of R& I & fee	Dy No.745, dated 18-04-2014, Rs.20000/- dated 18-04-2014 (Verified by R&I Incharge)
	Composition	Each 10ml ampoule contains: - Ferric carboxymaltose equivalent to elemental Iron …… 500mg
	Pharmacological Group	Hematinic
	Type of Form	Form-5 (Duplicate dossier)
	Finished Product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Bio-Maltose Injection by Bio-Lab
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	

b. Deferred cases

1557	**Name and address of manufacturer / Applicant**	**M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 5/80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5454 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each tablet contains: Amlodipine (as besylate) …5mg Telmisartan …80mg.
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's/ As per SRO

	Approval status of product in Reference Regulatory Authorities.	Telmisartan and amlodipine tablet 5mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved)
	Me-too status	Telsarta-A 5/80 Tablet by M/s Pharmevo (Reg#073762)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. • Firm has not submitted evidence of double layer compression machine.
	Decision of 288th meeting: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.	
	Firm's reply: Firm has submitted copy of commercial invoice of ZP 25 Tablet press machine from M/s Sinoped (China) Ltd., along with Installation qualification protocol.	
	Decision: Approved. Firm shall submit IQ, OQ & PQ reports for bi-layer compression machine before issuance of registration letter.	
1558	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 5/20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5452 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each tablet contains: Amlodipine (as besylate) …5mg Telmisartan …20mg.
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. • Firm has not submitted evidence of double layer compression machine. • Approval status of product in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Decision of 288th meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.	
	Firm's response: Firm has submitted revised composition as under along with submission of fee of Rs. 30,000/- vide deposit slip#8615862525:	

	"Each tablet contains: Amlodipine (as besylate) …5mg Telmisartan …20mg."	
	Decision: Approved as per following label claim: "**Each tablet contains:** **Amlodipine (as besylate) …5mg** **Telmisartan …20mg."** **Firm shall submit IQ, OQ & PQ reports for bi-layer compression machine before issuance of registration letter before issuance of registration letter.**	
1559	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 5/40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5453 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each tablet contains: Amlodipine (as besylate) …5mg Telmisartan …40mg.
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x7's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan and amlodipine tablet 5mg/40mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved)
	Me-too status	Telsarta-A 5/40 Tablet by M/s Pharmevo (Reg#073763)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. • Firm has not submitted evidence of double layer compression machine.
	Decision of 288th meeting: Deferred for following: • Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's reply: • Firm has submitted copy of commercial invoice of ZP 25 Tablet press machine from M/s Sinoped (China) Ltd., along with Installation qualification protocol. • Applied formulation has been approved by TGA of Australia.	
	Decision: Approved. Firm shall submit IQ, OQ & PQ reports for bi-layer compression machine before issuance of registration letter before issuance of registration letter	
1560	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 5/40mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5453 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each tablet contains: Amlodipine (as besylate) …5mg Telmisartan …40mg.
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack size & Demanded Price	2x7's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan and amlodipine tablet 5mg/40mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved)
	Me-too status	Telsarta-A 5/40 Tablet by M/s Pharmevo (Reg#073763)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. • Firm has not submitted evidence of double layer compression machine.
	Decision of 288th meeting: Deferred for following: • Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's reply: • Firm has submitted copy of commercial invoice of ZP 25 Tablet press machine from M/s Sinoped (China) Ltd., along with Installation qualification protocol. • Applied formulation has been approved by TGA of Australia.	
	Decision: Approved. Firm shall submit IQ, OQ & PQ reports for bi-layer compression machine before issuance of registration letter before issuance of registration letter	
1561	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Telsar-AM Tablet 10/80mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5455 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each tablet contains: Amlodipine (as besylate) …10mg Telmisartan …80mg.
	Pharmacological Group	Angiotensin II antagonists and calcium channel blockers
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x7's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmisartan and amlodipine tablet 10mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved)
	Me-too status	Telsarta-A 10/80 Tablet by M/s Pharmevo (Reg#073767)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet. • Firm has not submitted evidence of double layer compression machine.
	Decision of 288th : Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.	
	Firm's reply: Firm has submitted copy of commercial invoice of ZP 25 Tablet press machine from M/s Sinoped (China) Ltd., along with Installation qualification protocol.	
	Decision: Approved. Firm shall submit IQ, OQ & PQ reports for bi-layer compression machine before issuance of registration letter before issuance of registration letter	

1562	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Erotine 150mg Capsule
	Diary No. Date of R& I & fee	Form-5 Dy.No 5438 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each capsule contains: Erdosteine…150mg
	Pharmacological Group	Mucolytics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2x10's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Erdozet Capsules 150mg by M/s S.J&G (Reg#073809)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.
	Decision of 288th meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Firm's response:	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	

1563	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Erotine 175mg Capsule
	Diary No. Date of R& I & fee	Form-5 Dy.No 5439 (14-02-2018) Rs.20,000/- 14-02-2018
	Composition	Each capsule contains: Erdosteine…175mg
	Pharmacological Group	Mucolytics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2x10's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Not confirmed.
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Decision: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Firm's reply: Firm has submitted revised composition as under along with fee of Rs. 30,000/- vide deposit slip# 5731087529: "Each 5ml of reconstituted suspension contains: Erdosteine ……. 175mg" Following references have also been verified for revised composition: • Erdos suspension 175mg of M/s Platinum Pharma (Reg#053048)	

	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1564	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt) Ltd, Plot # 129, sunder estate, Raiwind road Lahore
	Brand Name +Dosage Form + Strength	Ossovit-D Suspension
	Diary No. Date of R& I & fee	Dy No.1370.23-12-2013, Rs.20,000/-
	Composition	Each 5ml contains: Ossein Mineral Complex MS ...250mg corresponding to Calcium……..53.5mg Phosphorous…24.8mg Residual Mineral Salt…..7.50mg Collagen……67.50mg Other Proteins…..20mg Trace Elements …..F'Mg,Fe,Zn,Cu,Ni Corresponding to approx 132mg hydroxyapatite
	Pharmacological Group	Vitamin and calcium phosphorus supplement
	Type of Form	Form-5
	Finished Product Specification	Innovator Specs
	Pack size & Demanded Price	60 ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Intig (sami)
	GMP status	GMP Certificate No.70/2021-DRAP(FID/2061717-540) Dated 08-09-21
	Decision of 243rd meeting: Deferred for or confirmation of Atomic Absorption by Area FID.	
	Firm's response: Firm has requested for change in dosage form of the applied formulation from suspension to tablet stating that their another application for suspension dosage form has been considered in 296th meeting. Firm has also submitted following composition along with Form 5 and full fee of Rs. 30,000 vide deposit slip# 96213800648. Each Film Coated Tablet Contains: Vitamin D… 400 IU Ossein Mineral Complex…830mg Corresponding to Calcium…177.6mg Phosphorus…82.2mg Residual Mineral Salts…24.8mg Collagen…224mg Other Proteins…88.4mg Trace Elements… Fi,mg,Fe,Zn,Cu,Ni. Corresponding To Approximately 440mg Hydroxyapatite	
	Decision: Registration Board did not accede for change of dosage form hence instant registration application was declared as disposed off	

1565	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Sitatin-Plus Tablet 25/500mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5447 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…25mg Metformin hydrochloride …500mg
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications

	Pack size & Demanded Price	10's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Sitaglu Met Tablets 25/500 by M/s Hilton (Reg#073734)
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.
	Decision of 288th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's response: Firm has submitted revised composition as under with fee of Rs. 30,000/- vide deposit slip# 2458721632: Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…50mg Metformin hydrochloride …500mg	
	Decision: Approved with Innovator's specifications as per following label claim: **Each film coated tablet contains:** **Sitagliptin (as phosphate monohydrate)…50mg** **Metformin hydrochloride …500mg**	
1566	Name and address of manufacturer / Applicant	M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Sitatin-Plus Tablet 25/1000mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 5448 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…25mg Metformin hydrochloride …1000mg
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Not confirmed
	GMP status	Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Decision of 288th meeting: Deferred for following: • Evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting	
	Firm's response: Firm has submitted revised composition as under with fee of Rs. 30,000/- vide deposit slip# 16580131327 : Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…50mg Metformin hydrochloride …1000mg	
	Decision: Approved with Innovator's specifications as per following label claim: **"Each film coated tablet contains:** **Sitagliptin (as phosphate monohydrate) …. 50mg** **Metformin hydrochloride …1000mg"**	
1567	Name and address of manufacturer / Applicant	M/s. Wimits Pharmaceuticals (Pvt) Ltd, Plot # 129, sunder estate, Raiwind road Lahore
	Brand Name +Dosage Form + Strength	**Grofast Suspension**
	Diary No. Date of R& I & fee	Dy No.1309 ,24-6-14, Rs.20000/-

	Composition	Each 5ml contains: - Vitamin-D ……400 IU Ossein Mineral Complex….400 mg
	Pharmacological Group	Vitamin and calcium phosphorus supplement
	Type of Form	Form-5
	Finished Product Specification	Innovator Specs
	Pack size & Demanded Price	120 ml As per PRC
	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Not provided
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator.	Firm has submitted following: • Section approval was provided for general syrup section. • Cosmocol-D by Caraway Pharmaceutical is claimed to be reference but the strength is different. Not found in reference authorities
	Previous Decision	Registration Board in its 269th meeting decided as under: Deferred for evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board and me-too status as stated reference is incorrect.
	Evaluation by PEC (AD PEC-XII)	Me-Too product Osnate –D suspension registered in the name of M/s. AGP Ltd., Karachi (Reg.no. 070854) Firm provide the evidence of letter of FID in which the officer verified the availability of atomic absorption spectrophotometer vide letter no. 12314/2017-DRAP (L-I) dated 15-09-2017.
	Decision of 296th meeting: Deferred for the submission of complete composition of Ossein Mineral Complex by the firm.	
	Firm's response: Firm has submitted revised master formulation including composition of Ossein mineral complex as under: "Each 5ml contains: Vitamin D.....400IU Ossein Mineral Complex …… 400mg Equivalent to: Calcium……85.59mg Phosphorous……39.61mg Residual Mineral Salt…12mg Collagen……...107.95mg Other Protein……32mg Trace Element … (Fi, Mg, Fe, Zn, Cu, Ni.)" Firm has also submitted letter No. 12314/2017-DRAP (L-I) dated 15-09-2017 declarig availability of Atomic Absorption spectrophotometer.	
	Decision: Approved with Innovator's specifications and change of brand name as per following label claim: **"Each 5ml contains:** **Vitamin D.....400IU** **Ossein Mineral Complex …… 400mg** **Equivalent to:** **Calcium……85.59mg** **Phosphorous……39.61mg** **Residual Mineral Salt…12mg** **Collagen……...107.95mg** **Other Protein……32mg** **Trace Element … (Fi, Mg, Fe, Zn, Cu, Ni.)"**	

	The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product composition as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1568	Name and address of manufacturer/ Applicant	M/s Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.
	Brand Name + Dosage Form + Strength	ACTIDOL CF Tablet
	Composition	Each Tablet Contains: Paracetamol ……. 500 mg Caffeine ……. 30 mg Chlorpheniramine Maleate …...… 2 mg
	Diary No. Date of R & I & fee	Dy. No 11793 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Analgesic/Antipyretic
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)
	Remarks of the Evaluator	Deficiency letter was issued to firm for submission of evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board. Firm has submitted reply vide dairy No. 1018 (PEC DRAP) dated 13-05-2022 along with pre-registration fee of 30,000 vide challan No.78017563568 dated 13-05-2022 and submitted revised form -5 mentioning revised label claim and composition for standardization of formulation as under:

Composition	Each Film Coated Tablet Contains: Paracetamol……325 mg Tramadol Hcl…….37.5mg
Pharmacological Group	Anti-Pyretic/Analgesic
Finished Product specification	Innovators specification
Pack size & Demanded Price	10's, As per SRO
Approval status of product in Reference Regulatory Authorities	Ultracet Tablet by M/s Janssen Ortho, (USFDA approved)
Me-too status	Forgesil Tablet by M/s Genome Pharmaceutical (Reg No:080874

	Decision of 317th meeting: Deferred for review as firm has changes the ingredients in subsequent application.

	Firm's reply: Firm has submitted that on basis of not finding the approval status of product in requested to reconsider for approval of the product with changed composition.	
	Decision: Registration Board did not accede for change of active ingredient in the applied formulation and deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
1569	**Name and address of manufacturer / Applicant**	M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan
	Brand Name + Dosage Form + Strength	Jolip 10mg Tablet
	Composition	Each Tablet Contains: Zolpidem as tartrate…10mg
	Diary No. Date of R& I & fee	Dy. No 16246 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Pharmacological Group	Sedative agents
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 14'S /As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status (with strength and dosage form)	Olida 10mg Tablets of M/s Glitz Pharmaceuticals, Islamabad (Reg.# 081418)
	GMP status	The panel recommended renewal of DML, inspection date 03/05/2019.
	Remarks of Evaluator II: RRA product is film coated tablet	
	Decision of 291st meeting: Deferred for consideration on its turn with respect to the queue	
	Evaluation by PEC: The case is presented now for consideration of Registration Board as per queue.	
	Decision: Approved.	
1570	**Name and address of manufacturer / Applicant**	M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan
	Brand Name + Dosage Form + Strength	Jadol-P 325/37.5 mg Table
	Composition	Each Tablet Contains: Paracetamol…325mg Tramadol as HCl…37.5mg
	Diary No. Date of R& I & fee	Dy. No 16246 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10'S /As per SRO
	Approval status of product in Reference Regulatory Authorities	ULTRACET by Janssen Pharmaceuticals, Inc. MHRA Approved
	Me-too status (with strength and dosage form)	Misadol Plus tablet of M/s Mission pharma
	GMP status	The panel recommended renewal of DML, inspection date 03/05/2019.
	Remarks of Evaluator II: RRA product is film coated tablet	
	Decision of 291st meeting: Deferred for consideration on its turn with respect to the queue	
	Evaluation by PEC: The case is presented now for consideration of Registration Board as per queue.	
	Decision: Approved.	
1571	**Name and address of manufacturer / Applicant**	M/s Jinnah Pharmaceuticals Pvt. Ltd. 13 km, Lahore Road, Multan
	Brand Name + Dosage Form + Strength	Jampro 5mg Tablets
	Composition	Each Tablet Contains: Procyclidine as HCl…….5mg

	Diary No. Date of R& I & fee	Dy.No 16245 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Pharmacological Group	Anti-cholinergic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10'S /As per SRO
	Approval status of product in Reference Regulatory Authorities	Kemadrin (uncoated) Tablets 5mg by Aspen Pharma (MHRA Approved)
	Me-too status (with strength and dosage form)	Kemadrin Tablet by GSK (Reg# 000363)
	GMP status	The panel recommended renewal of DML, inspection date 03/05/2019.
	Remarks of Evaluator II:	
	Decision of 291st meeting: Deferred for consideration on its turn with respect to the queue	
	Evaluation by PEC: The case is presented now for consideration of Registration Board as per queue.	
	Decision: Approved.	
1572	**Name and address of manufacturer / Applicant**	**M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Saprofen 200mg/5ml
	Composition	Each 5ml Contains: Ibuprofen …… 200mg
	Diary No. Date of R& I & fee	Dy. No. 12224 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Non-selective COX inhibitors
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	90ml, 450ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ibuprofen 100mg/5ml Suspension, MHRA approved.
	Me-too status	Tercica 100mg/5ml Suspension, Sami, Karachi, Reg. No. 061206
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated. • Firm has submitted signed form 5 along with all the enclosures of form 5. • In initially submitted dossier firm has claimed each 5ml contains 200mg of Ibuprofen. However, in newly submitted enclosures of Form 5 they revised their label claim to each 5ml contains 100mg of Ibuprofen. • They have claimed BP specs.
	Decision of 321st meeting: Deferred for clarification of the label claim for the applied formulation.	
	Firm's reply: Firm has submitted fee of Rs. 7,500/-vide deposit slip# 514007007664 alongwith Form 5 with following composition: "Saprofen 100mg/5ml Each 5ml Contains: Ibuprofen …… 100mg"	
	Decision: Approved with USP specifications per following specifications as per following label claim: **"Saprofen 100mg/5ml** **Each 5ml Contains:** **Ibuprofen …… 100mg"** **The firm shall submit differential fee of Rs. 22,500/- for correction/pre-approval change in product composition as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.**	
1573	**Name and address of manufacturer / Applicant**	**M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore**

	Brand Name +Dosage Form + Strength	Lsprd 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride ……..…50mg
	Diary No. Date of R& I & fee	Dy. No. 12208 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Benzamides
	Type of Form	Form 5
	Finished Product Specification	Innovators specifications
	Pack size & Demanded Price	1x10's, 3x10's, 6x10's, 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	LEVOPRAID® 50 mg Tablets by TEOFARMA Srl. Approved by AIFA
	Me-too status	Sulvo Tablets 50mg. Reg. No. 31748
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Submitted form 5 and its enclosures are for Itopride HCl instead of Levosulpiride.
	Decision of 321st meeting: Deferred for clarification of the label claim for the applied formulation.	
	Firm's reply: Firm has submitted fee of Rs. 7,500/-vide deposit slip# 040083095964 alongwith Form 5 and its enclosures.	
	Decision: Approved. The firm shall submit differential fee of Rs. 22,500/- for correction/pre-approval change in composition as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1574	**Name and address of manufacturer / Applicant**	**M/s Sapient Pharma 123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore**
	Brand Name +Dosage Form + Strength	Sinita 2mg/ml syrup
	Composition	Each ml Contains: Cinitapride Hydrogen Tartrate……..…2mg
	Diary No. Date of R& I & fee	Dy. No. 12226 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Not submitted. Available in USP and BP
	Pack size & Demanded Price	90ml, 450ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg/5 ml Oral solution, CIMA approved.
	Me-too status	Gutt oral solution. Reg. No. 75278
	GMP status	Copy of GMP certificate No. 80/2020-DRAP (AD-199285-703) dated 22-04-2020 issued on the basis of inspection conducted on 18-11-2019 is submitted.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• The pharmacological group has not been provided. Mention it as Propulsives. • Revise Each ml Contains: Cinitapride Hydrogen Tartrate…2mg to Each 5ml Contains: Cinitapride as Hydrogen Tar trate…1mg, and fill serial No. 04 of the enclosure accordingly. • You have provided the pack size as 1x14's tablet. Jsutify/revise. • Submit all the requirements /documents as per enclosure of Form 5 along with submission of applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.
	Decision of 321st meeting: Deferred for the following; • Pharmacological group for the applied formulation.	

	• Revision of label claim as per reference product along with submission of full fee. • Revision of pack size from tablet to syrup formulation. • Submission of all the requirements /documents as per enclosure of Form 5..
	Firm's reply: Firm has submitted fee of Rs. 7,500/-vide deposit slip# 2806662406 alongwith Form 5 and its enclosures for following revised composition: Sinita 1mg/5ml syrup Each 5ml Contains: Cinitapride as Hydrogen Tartrate ……1mg
	Decision: Approved as per following label claim: **Sinita 1mg/5ml syrup** **Each 5ml Contains:** **Cinitapride as Hydrogen Tartrate ……1mg** **The firm shall submit differential fee of Rs. 22,500/- for correction/pre-approval change in product composition as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.**

Case no. 07 Priority registration of Isoflurane Inhalational Solution

DRAP in its 143rd meeting of Authority held on 05th August, 2022, keeping in view of essentiality, criticality of isoflurane and pursuance from Government of Punjab to ensure its availability in Pakistan decided that registration application of Isoflurane shall be considered "out of queue" by the Registration Board.
PHARMA LIMITED. Sy. Nos. 7-70, 70/1 & 70/2, Digwal (D), Kohir (M), SANGAREDDY (D), Telangana State, India.
Available applications of Isoflurane 100ml & 250ml liquid for inhalation, are presented below:

1575.	**Name, address of Applicant / Importer**	M/s RA Healthcare (SMC-Pvt) Ltd. 2nd Floor, Building No 50, Mir Arcade, Mini Commercial Phase 7, Bahria Town, Islamabad
	Details of Drug Sale License of importer	**License No:** 01-374-0176-049615D **Address:** RA Healthcare 2nd Floor, Building No 50, Mir Arcade, Mini Commercial Phase 7, Bahria Town, Islamabad **Address of Godown:** NA **Validity:** 11-01-2022 **Status:** Drug Licence by way of Distributor. Firm has also submitted receipt of application for renewal of DSL.
	Name and address of marketing authorization holder (abroad)	M/s Baxter Healthcare Corporation, 1baxter Parkway, Deerfield, IL 60015 United States of America Route 3-Km144.2, Guayama, Puerto, Rico 00783 (USA)
	Name, address of manufacturer(s)	M/s Baxter Healthcare Corporation. Route 3-Km144.2, Guayama, Puerto, Rico 00783 (USA)
	Name of exporting country	United States of America
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized COPP (Certificate# MBP9-K62W) issued by United States Food & Drug Administration valid till 21-02-2023 • Free Sale status: The COPP endorses the free sale status of the applied product in United States of America • GMP: The COPP declares GMP compliant status of the manufacturer.	
	Details of letter of authorization / sole agency agreement Copy "Letter of Authorization" dated 21-07-2022, issued by M/s Baxter healthcare Corporation, in the name of M/s RA Healthcare (SMC-Pvt) Ltd., 2nd Floor, Building No 50, Mir Arcade,	

	Mini Commercial Phase 7, Bahria Town, Islamabad, Pakistan for the applied product of "**Aerrane (isoflurane)"**	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 30589 dated 28-10-2022
	Details of fee submitted	Rs. 75,000/- dated 25-10-2022
	The proposed proprietary name / brand name	**Aerrane 250ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250 contains: Isoflurane ……. 100%v/v
	Pharmaceutical form of applied drug	Liquid for Inhalation
	Pharmacotherapeutic Group of (API)	General Anaesthetic
	Reference to Finished product specifications	USP
	Proposed Pack size	250ml
	Proposed unit price	Will be provided at the time of pricing.
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Forane of M/s Getz Pharma.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Baxter Healthcare Corporation. Route 3-Km144.2, Guayama, Puerto, Rico 00783 (USA)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data f related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has referred to the stress studies under following conditions: • Strong base • Various metals • UV radiation • Prolonged heating. Firm has submitted conclusion on basis of above conditions that isoflurane is a very stable substance under variety of conditions. Further firm has submitted that stability data for substance is not applicable as its 99.9% Active substance and there is no excipient in it.
	Module-III Drug Product:	Firm has submitted data of drug product, including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence Studies	Not applicable since applied formulation is Innovator product.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Amber colored, round, Type III glass bottles with a polypropylene cap with a poly-sealer liner.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The Long term stability study data is conducted at 30°C ±2°C / AH for 60 months. Firm has stated that since the container closure system is impermeable, humidity is not a factor during stability studies, long term and under accelerated conditions.
	Claimed shelf life	60 months.
1576.	**Name, address of Applicant / Importer**	M/s RA Healthcare (SMC-Pvt) Ltd. 2nd Floor, Building No 50, Mir Arcade, Mini Commercial Phase 7, Bahria Town, Islamabad
	Details of Drug Sale License of importer	**License No:** 01-374-0176-049615D **Address:** RA Healthcare 2nd Floor, Building No 50, Mir Arcade, Mini Commercial Phase 7, Bahria Town, Islamabad **Address of Godown:** NA **Validity:** 11-01-2022 **Status:** Drug Licence by way of Distributor. Firm has also submitted receipt of application for renewal of DSL.

	Name and address of marketing authorization holder (abroad)	M/s Baxter Healthcare Corporation, 1baxter Parkway, Deerfield, IL 60015 United States of America Route 3-Km144.2, Guayama, Puerto, Rico 00783 (USA)
	Name, address of manufacturer(s)	M/s Baxter Healthcare Corporation. Route 3-Km144.2, Guayama, Puerto, Rico 00783 (USA)
	Name of exporting country	United States of America
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Original legalized COPP (Certificate# 6ZXDKQMW) issued by United States Food & Drug Administration valid till 21-02-2023 • Free Sale status: The COPP endorses the free sale status of the applied product in United States of America • GMP: The COPP declares GMP compliant status of the manufacturer.	
	Details of letter of authorization / sole agency agreement Copy "Letter of Authorization" dated 21-07-2022, issued by M/s Baxter healthcare Corporation, in the name of M/s RA Healthcare (SMC-Pvt) Ltd., 2nd Floor, Building No 50, Mir Arcade, Mini Commercial Phase 7, Bahria Town, Islamabad, Pakistan for the applied product of "**Aerrane (isoflurane)"**	
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 30590 dated 28-10-2022
	Details of fee submitted	Rs. 75,000/- dated 25-10-2022
	The proposed proprietary name / brand name	**Aerrane 100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each100ml contains: Isoflurane ……. 100%v/v
	Pharmaceutical form of applied drug	Liquid for Inhalation
	Pharmacotherapeutic Group of (API)	General Anaesthetic
	Reference to Finished product specifications	USP
	Proposed Pack size	250ml
	Proposed unit price	Will be provided at the time of pricing.
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Forane of M/s Getz Pharma.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general

		properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Baxter Healthcare Corporation. Route 3-Km144.2, Guayama, Puerto, Rico 00783 (USA)
	Module-III Drug Substance:	Firm has submitted detailed drug substance data f related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has referred to the stress studies under following conditions: • Strong base • Various metals • UV radiation • Prolonged heating. Firm has submitted conclusion on basis of above conditions that isoflurane is a very stable substance under variety of conditions. Further firm has submitted that stability data for substance is not applicable as its 99.9% Active substance and there is no excipient in it.
	Module-III Drug Product:	Firm has submitted data of drug product, including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence Studies	Not applicable since applied formulation is Innovator product.
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
	Container closure system of the drug product	Amber colored, round, Type III glass bottles with a polypropylene cap with a poly-sealer liner.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The Long term stability study data is conducted at 30°C ±2°C / AH for 60 months.

		Firm has stated that since the container closure system is impermeable, humidity is not a factor during stability studies, long term and under accelerated conditions.
	Claimed shelf life	60 months.
	Remarks of Evaluator: Firm has submitted that process validation is not applicable since the manufacturing process for the drug product consists only of packaging the drug substance.	
	Decision: Registration Board approved the applications for Aerrane 250ml Aerrane 100ml as per policy for inspections of manufacturer abroad. Firm shall submit process validation report before issuance of registration letter.	

Case No. 01 Registration applications of New License

a. New Cases

Case No. 01: M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi

M/s Biogen Life Sciences, Rawalpindi has been granted new license (DML No. 000911) by way of formulation by Licensing division DRAP dated 13-02-2020. Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	Considered till 317th RB meeting		Freshly applied	
	No of molecules	No of products	No of molecules	No of products
Dry Vial section (Cephalosporin)	03	12	-	-
Dry suspension section (Cephalosporin)	01	02	01	02
Capsule section (Cephalosporin)	02	02	01	01
Ampoule Section SVP (General)	05	07	-	-
Capsule section (General)	03	05	-	-
Dry Vial section (General)	03	04	-	-
Soft gel capsule general section	02	03	-	-
Hydrocortisone injection (steroid)	01	03	-	-
Sachet section (General)	01	01	-	-
Dry Vial section (Carbapenem)	02	03	-	-
Cream section (general)	02	02	-	-
Ointment section (General)	01	01	-	-
Lotion section (General)	01	01	-	-
Infusion Section (General)	02	02	-	-
Tablet (General) Section	01	01	01	01

Capsule section (Cephalosporin): 01 Molecule / 01 Product		
1577.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Capsule section (Cephalosporin).

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20727: 22-07-2022
	Details of fee submitted	PKR 30,000/-: 15-07-2022
	The proposed proprietary name / brand name	**CEFIBIO 200mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	White to off white powder contained in white hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixima Normon 200 Mg Hard Capsules EFG **(Spain** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols,

		control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefim 200mg Capsule of Hilton Pharma. Firm has submitted results of CDP for their product against Cefim 200mg Capsule of Hilton Pharma. Firm has tested CDP in three dissolution medium and the results of f2 factor are within the acceptable limit.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00244/135/2021		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T2001C	T2002C	T2003C
Batch Size	1000 capsule	1000 capsule	1000 capsule
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	08-10-2021	08-10-2021	08-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 30-06-2021 specifying purchase of 25Kg Cefixime (compacted).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Our HPLC system is 21 CFR compliant

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.	Firm has submitted copy of specifications of the drug substance from API manufacturer as well as Biogen Life Sciences.
2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the drug substance from Biogen Life Sciences.
3.	Justification is required since the applied product is developed according to Japanese Pharmacopoeial monograph which is for 100mg and 50mg capsule. Moreover, Drug Regulatory Authority of Pakistan has published the monograph for 400mg and 200mg Cefixime as Trihydrate capsule vide notification No.F.14-1/2022-PEC dated 14th March, 2022.	Firm has submitted that they have revised the product specifications in March 2022 after the notification of new monograph by DRAP and have performed 6th month stability testing using the revised monograph.

Decision: Approved with Manufacturer's specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

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

Dry suspension section (Cephalosporin): 01 Molecule / 02 Product

1578.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry suspension section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8317: 15-03-2021

	Details of fee submitted	PKR 20,000/-: 03-03-2021
	The proposed proprietary name / brand name	**GEN-ONE 125mg/5ml Dry suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cephradine as monohydrate……125mg
Evaluation by PEC[3]: • Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.		
Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.** • **Submission of fee of Rs. 30,000 since the title of the firm has been changed from Biogen Pharmaceuticals to Biogen Life Sciences, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**		
1579.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry suspension section (Cephalosporin).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8318: 15-03-2021
	Details of fee submitted	PKR 20,000/-: 03-03-2021
	The proposed proprietary name / brand name	**GEN-ONE 250mg/5ml Dry suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cephradine as monohydrate……250mg
	Pharmaceutical form of applied drug	White to off white powder filled in amber glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Nicef Syrup 250mg/5ml **(MHRA** Approved)
	For generic drugs (me-too status)	Velosef 250mg suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information

		related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Velosef suspension.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00203/163/2020		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-088	T-089	T-090
Batch Size	500 bottles	500 bottles	500 bottles

Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	10-06-2020	10-06-2020	10-06-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 07-04-2020 specifying purchase of 10Kg Cephradine (Micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Firm was issued letter of shortcoming dated 14-06-2021 with following observations.

- The method of analysis of the drug substance of Pharmagen Limited submitted in section 3.2.S.4.2 is different from BP as well as USP monograph. Justification is required in this regard.
- Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.
- Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "*Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"* Further specify how the testing of drug substance was carried out without performing verification studies.
- Submit COA of relevant batch of drug substance used in product development and stability studies from both drug substance as well as drug product manufacturer in section 3.2.S.4.4.
- Justify how the batch No 00203/163/2020 was tested by Biogen Pharma and declared pass without testing the cephalexin contents.
- The drug substance manufacturer specify BP specs for the drug substance, justify how Biogen pharma can declare the same product as complying with USP specs.
- Justify the submission of reference standard or material in section 3.2.S.5 in which USP reference standard is used against a drug substance which complies BP specifications.
- Submit COA of cephalexin reference standard which is also required in the analysis of drug substance.
- Justify the selection of excipients in the master formulation, since your qualitative composition is different from that of reference product.
- Justify why drug-excipient compatibility studies is not performed while the formulation is qualitatively different from that of reference product.
- Justify your master formulation without any buffer, while the reference product as well as USP monograph specifies that the suspension contains a suitable buffer.
- Justify why comparative dissolution studies of the product is not conducted against the reference product.
- Specify the details regarding Batch number, manufacturing date and expiry date of the product against which pharmaceutical equivalence was performed.

- Provide preservative effectiveness studies for your formulation since it contains a preservative in the formulation.
- Justify the analytical procedure of drug product in which the assay method is different from that specified in USP. How the product complies USP specifications when the method is different from USP.
- Justify how the assay testing is carried out without using the resolution solution.
- Justify how the analysis of cephradine is conducted without adding the peak response of cephalexin and using cephalexin RS.
- The analytical method used in verification studies is different from that specified in USP monograph. Justify how this method can be considered accurate and reliable.
- Justify how the concentrations of the standard solution were selected for measuring accuracy and repeatability since the concentrations used in your study are totally different from those required in the assay testing of the product.
- Submit COA of working standard of cephradine which is required in the testing of product. The submitted COA was valid before use till 26-10-2016. Justify how you have used the working standard which was expired in 2016 for testing the product which is manufactured in 2020.
- The injection volume specified in analytical method is 10µL while the same mentioned on HPLC chromatograms is 20 µL.
- The retention time of cephradine mentioned in verification studies is 3 minutes while the retention time in HPLC chromatograms is 26 minutes. Justify how the verification studies are representative of the actual performance.
- USP monograph specifies that "relative retention time are about 0.8 for cephalexin and 1.0 for cephradine" while the relative retention time of cephalexin in your chromatograms is around 0.6 while the relative retention time for cephradine also varies. Justification is required in this regard.

Response by the firm:
The firm in its response dated 23-11-2022 submitted new stability study data of three newly manufactured trial batches. The evaluation os newly submitted data is as follows:

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00203/163/2020		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T#DP60	T#DP61	T#DP62
Batch Size	500 bottles	500 bottles	500 bottles
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	29-06-2021	29-06-2021	29-06-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 07-04-2020 specifying purchase of 10Kg Cephradine (Micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Firm has submitted following documents:

- Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.
- Verification studies of analytical method of drug substance.
- Master formulation having similar qualitative composition as per the reference product.
- Pharmaceutical equivalence against velosef suspension.
- Stability study data along with HPLC chromatograms and raw data sheets showing calculation of results of assay based on sum of cephradine and cephalexin peak areas.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit fee of Rs. 30,000 for revision in stability data and for change in title of the firm from Biogen Pharmaceuticals to Biogen Life Sciences, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of registration letter.**

Tablet (General) Section: 01 Molecule / 01 Product

1580.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Tablet section (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29758: 20-10-2022
	Details of fee submitted	PKR 30,000/-: 15-07-2022
	The proposed proprietary name / brand name	**LINZOGEN 600mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Linezolid……600mg
	Pharmaceutical form of applied drug	White Colored, oblong, biconvex film coated tablets
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	Innovator's specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Nezkil Tablet by Asian continental
	Name and address of API manufacturer.	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Zevoxid Tablet of Genome Pharma.

		Firm has submitted results of CDP studies in three dissolution medium for their product against Zevoxid Tablet of Genome Pharma.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance a nc nd the drug product.

STABILITY STUDY DATA

Manufacturer of API	Optrix Laboratories Pvt Ltd. Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M), Yadadri-Bhuvanagiri District Telangana India.		
API Lot No.	OT-LIU/06/20/008		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LZT001	LZT002	LZT003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	15-05-2021	15-05-2021	15-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 68951/TS/2021) dated 20-09-2021 valid till 19-09-2022. Firm has submitted copy of License Retention Certificate for License number 3/NG/TS/2015/B/G of M/s Optrix Laboratories Pvt Ltd. The license is permitted with validity upto 02-06-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 15-06-2020 specifying 25Kg Linezolid. The invoice is not attested by AD
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable. Our HPLC system are not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the drug substance from Biogen Life Sciences.

2.	Justify why the pharmaceutical equivalence studies were conducted against the comparator product instead of using innovator / reference product.	*Due to Easley Access of the comparator Zevoxid 600 mg Tablet in market that way the (Biogen Life Sciences) perform Pharmaceutical Equivalence studies with Zevoxid 600 mg Tablet*
3.	Provide evidence of import of drug substance since you have not submitted ADC attested invoice.	Firm has submitted copy of DHL invoice (No. C0206995) dated 29-04-2020 specifying 3.5kg linezolid.

Decision: Approved with Innovator's specifications.

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

Case No. 02: M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Swabi.

Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section:
1. Liquid Injectable Infusion (SVP) LDPE (General)
2. Liquid Injectable Infusion (LVP) LDPE (General)

Now the firm has submitted following applications as per the details mentioned in the table below:

	Previously considered		Freshly applied	
Name of Section	**No of molecules**	**No of products**	**No of molecules**	**No of products**
Liquid Injectable Infusion (SVP) LDPE (General)	01	03	01	01
Liquid Injectable Infusion (LVP) LDPE (General)	03	08	01	02

Liquid Injectable Infusion (SVP) LDPE (General): 01 Molecules / 01 Products

1581.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12293: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022
	The proposed proprietary name / brand name	**SAFEZOL IV Infusion 100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Metronidazole……500mg
	Pharmaceutical form of applied drug	Clear colorless to pale yellow solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Anti bacterials for systemic use: imidazole derivatives
	Reference to Finished product specifications	BP
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Otsuzol Infusion by Otsuka Pharma
	Name and address of API manufacturer.	Hubei Hongyuan Pharmaceutical Technology Co., Ltd. No. 3, Hongyuan Road, Fengshan Town, Luotian County, Huanggang City, Hubei Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.

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

STABILITY STUDY DATA

Manufacturer of API	Hubei Hongyuan Pharmaceutical Technology Co., Ltd. No. 3, Hongyuan Road, Fengshan Town, Luotian County, Huanggang City, Hubei Province China.		
API Lot No.	0182110063		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	133 liters	133 liters	133 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	27-01-2022	27-01-2022	27-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HB20180424) of Hubei Hongyuan Pharmaceutical Technology Co., Ltd. issued by China Food and Drug Administration. The certificate is valid till 30-07-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 2Kg Metronidazole.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted stability study data of 3 batches along with water loss test at each time

	chromatograms, Raw data sheets, COA, summary data sheets etc.	point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Justify why the test of sulphated ash is not specified in the drug substance specification although this tet is recommended in BP monograph.	*Sulphated ash test was not mentioned in BP 2022.* **Firm has not submitted any relevant response.**
2.	Provide COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	**Firm has not submitted any response.**
3.	Provide description of pharmaceutical development as per the CTD guidance document which specifies that "A brief information on the pharmaceutical development shall be included. This information specifies the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed".	*Copy attached for master formulation and method of manufacturing in detail and proper information as per the CTD guidance regarding justification of formulation. And method of manufacturing.* **Firm has not submitted any relevant response.**
4.	You have mentioned "not applicable" for drug substance in section 3.2.P.2.1.1. Justify why you have mentioned not applicable and also provide information as per the CTD guidance document which specifies that "Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product."	*The compatibility of the drug substance with excipients listed in 3.2.P.1 should be discussed. Additionally, key physicochemical characteristics (e.g., water content, solubility, and particle size distribution, polymorphic or solid state form) of the drug substance that can influence the performance of the drug product should be discussed. For combination products, the compatibility of drug substances with each other should be discussed as per the CTD guidance.* **Firm has not submitted any relevant response.**
5.	Provide information regarding excipients added in the formulation in section 3.2.P.2.1.2.	*The choice of excipients listed in 3.2.P.1, their concentration, and their characteristics that can influence the drug product performance should be discussed relative to their respective functions.* **Firm has not submitted any relevant response.**
6.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*We have studied our comparator product & found that they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity.* **Firm has not submitted any relevant response.**
7.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation.* **Firm has not submitted any relevant response.**
8.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**

9.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
10.	Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients.	**Firm has not submitted any response.**
11.	Justify why the assay test mentioned in your analytical method is completely different from that spcifed in latest edition of BP monograph in terms of sample solution preparation, media in which sample solution is to be diluted and the calculation formula and procedure.	*Our analytical method is BP 2022* **Firm has not submitted any relevant response.**
12.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies of the analytical method of drug product in section 3.2.P.5.3.* **Firm has submitted process validation report instead of analytical method verification.**
13.	Provide COA of working standard / reference standard actually used in the analysis of drug product in section 3.2.P.6 instad of providing COA of the drug substance commercial lot.	**Firm has submitted COA of the drug substance commercial lot as COA of working standard.**
14.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily sterilize our product at 121c. to make our product sterile*
15.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
16.	Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section.	**Firm has not submitted any response.**
17.	Provide information in section 3.2.P.8.2 as per the CTD guidance document since you have mentioned "not applicable" in this section.	**Firm has not submitted any response.**
18.	The assay results of batch T-001 at batch analysis stage (section 3.2.P.5.4) shows 100% results while the initial stability results (section 3.2.P.8.3) performed on the same day show 104%. Justify how significant difference in results exists on the same date.	*Assay limits are 95-110% in BP 2022.* **Firm has not submitted any relevant response.**
19.	The stability data sheet for batch T001 shows that the assay result at initial time point for accelerated and real time studies are different. Clarification is required in this regard.	**Firm has not submitted any response.**
20.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*Bottles placed in stability chamber were with simple cap not with Euro CAP.*
21.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*65 bottles in real stabilty chamber.* *80 bottles in accelerated stabilty chamber.*
22.	Justify why the assay testing procedure adopted during the stability studies is completely different from BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **Firm has not submitted any relevant response. The assay method of the firm is different from BP monograph in terms of sample solution preparation, media in which sample solution is to be diluted and the calculation formula and procedure.**
23.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.*

	guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	**Firm has not submitted any relevant response.**
24.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**

Decision: Deferred for following submissions:

- **Scientific justification why the test of sulphated ash is not specified in the drug substance specification although this tet is recommended in BP monograph.**
- **COA of reference standard actually used in the analysis of drug substance.**
- **Description of pharmaceutical development of the applied product as per the CTD guidance document.**
- **Submission of details of drug substance in section 3.2.P.2.1.1 of Module 3.**
- **Submission of information regarding excipients added in the formulation in section 3.2.P.2.1.2.**
- **Pharmaceutical equivalence studies against the innovator's product.**
- **Submission of microbiological attributes of the drug product in section 3.2.P.2.5.**
- **Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.**
- **Submission of details of excipients used in the formulation in section 3.2.P.4.**
- **Scientific justification for performing assay test of drug product which is completely different from that spcifed in latest edition of BP monograph in terms of sample solution preparation, media in which sample solution is to be diluted and the calculation formula and procedure.**
- **Report of verification studies of the analytical method of drug product in section 3.2.P.5.3.**
- **Scientific justification for using commercial lot of API as working standard without any standardization.**
- **Submission of requisite information in section 3.2.P.8.1 and 3.2.P.8.2 as per the CTD guidance document.**
- **Scientific justification for the assay results of batch T-001 at batch analysis stage (section 3.2.P.5.4) which shows 100% results while the initial stability results (section 3.2.P.8.3) performed on the same day show 104%.**
- **Scientific justification for having different results at accelerated and real time conditions for batch T001.**
- **Scientific justification why test of water loss is not performed during the stability studies.**
- **Batch size of drug product stability batches in terms of no. of units.**

Liquid Injectable Infusion (LVP) LDPE (General): 01 Molecules / 02 Products

1582.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12294: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022
	The proposed proprietary name / brand name	**SAFESOL-RL IV Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride ……0.027g Potassium chloride……0.04g Sodium chloride…… 0.60g Sodium lactate….. ..0.32g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Could not be confirmed in applied strength
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Not submitted. **Calcium chloride:** Not submitted. **Potassium chloride:** Firm has submitted stability data of 3 batches of API as per zone IV-A conditions. **Sodium lactate:** Not submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product 'Sterifluid-RL Infusion by M/s FDL Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 liters	300 liters	300 liters

Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). **Calcium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee since innovator product specifies clalcium chloride dihydrate 0.027g/100ml while you have mentioned calcium chloride 0.027g/100ml.	*Applied formulation contains calcium chloride dihydrate as per BP innovator product also contains calcium chloride dihydrate. In master formulation typographic error found. New master formulation has been submitted.*

		Firm has not revised the label claim nor submitted any fee.
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	*our main competitor is FRONTIER DEXTROSE LIMITED PHARMA HATTAR having formulation sodium lactate 0.32g/100 ml which is same as our formulation 0.32g/100 ml.* **The available data base shows that Sterifluid RL Infusion (Reg # 052739) of M/s Frontier Dextrose Ltd contains Sodium Lactate 0.31gm**
3.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	*Typographic error found. Our product is BP Specifications.* **Firm has not submitted any fee**
4.	Submit verification studies of the Calcium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
5.	Provide actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer. Furthermore, the submitted stabilility sheets does not specify any batch number, manufacturing or expiry date etc.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
6.	Submit verification studies of the Potassium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
7.	Submit verification studies of the Sodium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
8.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
9.	Submit verification studies of the sodium lactate drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
10.	Provide actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
11.	The innovator's product is using 0.027g/100ml of clalcium chloride dihydrate while your formulation contains 0.027g/100ml of calcium chloride. Justify how your formulation is similar to that of innovator's product.	*Our formulation is similar to that of innovators product that is 0.027g/100ml of clacium chloride dihydrate.* **The submitted formulation as well as BMR shows that firm is using 0.027g/100ml of calcium chloride.**
12.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*Because they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product.* **Firm has not submitted any relevant response.**
13.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be*

		justified and presented to and approved by the regulatory authority prior to implementation. **Firm has not submitted any relevant response.**
14.	Justify how you can perform pharmaceutical equivalence against a product which have different quantitative composition as compared to your product.	*We cannot perform pharmaceutical equivalence against a product which has different quantitative composition to our product.* **Firm has not submitted any relevant response.**
15.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**
16.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
17.	Justify why the drug product specifications does not contain test of particulate matter.	*Product specification concentrate on quality of product till expiry with 100% efficiency .detail is given by literature support.* **Firm has not submitted any relevant response.**
18.	Justify why the acceptance criteria of all assay tests in pharmaceutical equivalence is not as per BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
19.	Justify why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
20.	Justify why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*Potassium test is according to BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
21.	Justify why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	*The method of sodium lactate is HPLC method in BP 2022. We give the HPLC print is attached with the file.* **Firm has used titration method as submitted in the application.**
22.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies.* **Firm has submitted process validation report instead of analytical method verification.**
23.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily sterilize our product at 121c. to make our product sterile*
24.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
25.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*At present we are using simple cap to reduce cost of our product but we have the facility of Eurocap machine facility.*
26.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*40 bottles in real stabilty chamber.* *60 bottles in accelerated stabilty chamber.*
27.	Justify why the stability studies have been performed using method and acceptance criteria which is completely different from that specified in BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**

28.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.* **Firm has not submitted any relevant response.**
29.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**
30.	The analytical method in section 3.2.P.5.2 specifies titration method for analysis of lactate while in stability studies you have provided single HPLC chromatogram for analysis in which the UV wavelength is also different from that specified in BP monograph.	*we have sumbitted the sodium lactate method on hplc according to BP2022.* **Firm has not submitted any relevant response.**
31.	Justify how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	**Firm has not submitted any response.**
32.	Provide details of the HPLC system, model along with details of the software available in your QC lab and status of its 21 CFR compliance.	*Our HPLC is LAB SOLUTION 21CFR software in our labortaory.*
33.	Provide evidence of atomic emission spectroscopy required for analysis of drug product as per BP monograph.	**Firm has not submitted any response.**
34.	Provide analysis report for all the testing performed through atomic emission spectroscopy.	**Firm has not submitted any response.**

Decision: Deferred for following submissions:

- **Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.**
- **Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.**
- **Report of verification studies of the Calcium chloride drug substance.**
- **Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.**
- **Report of verification studies of the Potassium chloride drug substance.**
- **Report of verification studies of the Sodium chloride drug substance.**
- **Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.**
- **Report of verification studies of the sodium lactate drug substance.**
- **Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.**
- **Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.**
- **Pharmaceutical equivalence studies against the innovator's product.**
- **Submission of microbiological attributes of the drug product in section 3.2.P.2.5.**
- **Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.**
- **Scientific justification for the drug product specifications which does not contain test of particulate matter.**
- **Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.**
- **Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**

	• **Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.** • **Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.** • **Report of verification studies of the analytical method of drug product.** • **Scientific justification why the test of water loss is not performed during the stability studies.** • **Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.** • **Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.** • **Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.** • **Batch size of drug product stability batches in terms of no. of units.**	
1583.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12295: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022
	The proposed proprietary name / brand name	**SAFESOL-RL IV Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride ……0.027g Potassium chloride……0.04g Sodium chloride…… 0.60g Sodium lactate….. ..0.32g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP

	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Could not be confirmed
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Not submitted. **Calcium chloride:** Not submitted. **Potassium chloride:** Firm has submitted stability data of 3 batches of API as per zone IV-A conditions. **Sodium lactate:** Not submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

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

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 liters	300 liters	300 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023.

		Sodium lactate: Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). **Calcium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee since innovator product specifies clalcium chloride dihydrate 0.027g/100ml while you have mentioned calcium chloride 0.027g/100ml.	*Applied formulation contains calcium chloride dihydrate as per BP innovator product also contains calcium chloride dihydrate. In master formulation typographic error found. New master formulation has been submitted.* **Firm has not revised the label claim nor submitted any fee.**
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	*our main competitor is FRONTIER DEXTROSE LIMITED PHARMA HATTAR having formulation sodium lactate 0.32g/100 ml which is same as our formulation 0.32g/100 ml.* **The available data base shows that Sterifluid RL Infusion (Reg # 052739) of M/s Frontier Dextrose Ltd contains Sodium Lactate 0.31gm**
3.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	*Typographic error found. Our product is BP Specifications.* **Firm has not submitted any fee**
4.	Submit verification studies of the Calcium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
5.	Provide actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer. Furthermore, the	**Firm has not submitted stability study data sheets for API from API manufacturer.**

	submitted stabilility sheets does not specify any batch number, manufacturing or expiry date etc.	
6.	Submit verification studies of the Potassium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
7.	Submit verification studies of the Sodium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
8.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
9.	Submit verification studies of the sodium lactate drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
10.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
11.	The innovator's product is using 0.027g/100ml of clalcium chloride dihydrate while your formulation contains 0.027g/100ml of calcium chloride. Justify how your formulation is similar to that of innovator's product.	*Our formulation is similar to that of innovators product that is 0.027g/100ml of clacium chloride dihydrate.* **The submitted formulation as well as BMR shows that firm is using 0.027g/100ml of calcium chloride.**
12.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*Because they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product.* **Firm has not submitted any relevant response.**
13.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation.* **Firm has not submitted any relevant response.**
14.	Justify how you can perform pharmaceutical equivalence against a product which have different quantitative composition as compared to your product.	*We cannot perform pharmaceutical equivalence against a product which has different quantitative composition to our product.* **Firm has not submitted any relevant response.**
15.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**
16.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
17.	Justify why the drug product specifications does not contain test of particulate matter.	*Product specification concentrate on quality of product till expiry with 100% efficiency .detail is given by literature support.* **Firm has not submitted any relevant response.**
18.	Justify why the acceptance criteria of all assay tests in pharmaceutical equivalence is not as per BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**

19.	Justify why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
20.	Justify why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*Potassium test is according to BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
21.	Justify why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	*The method of sodium lactate is HPLC method in BP 2022. We give the HPLC print is attached with the file.* **Firm has used titration method as submitted in the application.**
22.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies.* **Firm has submitted process validation report instead of analytical method verification.**
23.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily sterilize our product at 121c. to make our product sterile*
24.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
25.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*At present we are using simple cap to reduce cost of our product but we have the facility of Eurocap machine facility.*
26.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*40 bottles in real stabilty chamber.* *60 bottles in accelerated stabilty chamber.*
27.	Justify why the stability studies have been performed using method and acceptance criteria which is completely different from that specified in BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
28.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.* **Firm has not submitted any relevant response.**
29.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**
30.	The analytical method in section 3.2.P.5.2 specifies titration method for analysis of lactate while in stability studies you have provided single HPLC chromatogram for analysis in which the UV wavelength is also different from that specified in BP monograph.	*we have sumbitted the sodium lactate method on hplc according to BP2022.* **Firm has not submitted any relevant response.**
31.	Justify how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	**Firm has not submitted any response.**
32.	Provide details of the HPLC system, model along with details of the software available in your QC lab and status of its 21 CFR compliance.	*Our HPLC is LAB SOLUTION 21CFR software in our labortaory.*

33.	Provide evidence of atomic emission spectroscopy required for analysis of drug product as per BP monograph.	**Firm has not submitted any response.**
34.	Provide analysis report for all the testing performed through atomic emission spectroscopy.	**Firm has not submitted any response.**

Decision: Deferred for following submissions:

- **Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.**
- **Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.**
- **Report of verification studies of the Calcium chloride drug substance.**
- **Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.**
- **Report of verification studies of the Potassium chloride drug substance.**
- **Report of verification studies of the Sodium chloride drug substance.**
- **Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.**
- **Report of verification studies of the sodium lactate drug substance.**
- **Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.**
- **Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.**
- **Pharmaceutical equivalence studies against the innovator's product.**
- **Submission of microbiological attributes of the drug product in section 3.2.P.2.5.**
- **Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.**
- **Scientific justification for the drug product specifications which does not contain test of particulate matter.**
- **Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.**
- **Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
- **Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
- **Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.**
- **Report of verification studies of the analytical method of drug product.**
- **Scientific justification why the test of water loss is not performed during the stability studies.**
- **Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.**
- **Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.**
- **Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.**
- **Batch size of drug product stability batches in terms of no. of units.**

Case No. 03: M/s Pasteur and Fleming Pharmaceuticals (Pvt) Ltd. Hattar.

Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000945) dated 11-11-2021. The letter specifies following section:

- Tablet (Hormone)
- Tablet (General)
- Capsule (General)
- Dry Powder Suspension (General)
- Cream / Ointment Section (General)

Now the following applications have been marked to AD PEC-III as per the details mentioned in the table below:

Name of Section	**No of molecules**	**No of products**
Dry Powder Suspension (General)	01	02

Dry Powder Suspension (General): 01 Molecule / 02 Product

1584.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur and Fleming Pharmaceuticals (Pvt) Ltd. Plot No. P.70-A, Road No. 4, Phase-3, Industrial Area Hattar.**
	Name, address of Manufacturing site.	M/s Pasteur and Fleming Pharmaceuticals (Pvt) Ltd. Plot No. P.70-A, Road No. 4, Phase-3, Industrial Area Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000945) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000945) dated 11-11-2021. The letter specifies following section: • Tablet (Hormone) • Tablet (General) • Capsule (General) • Dry Powder Suspension (General) • Cream / Ointment Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28549: 07-10-2022
	Details of fee submitted	PKR 30,000/- : 30-09-2022
	The proposed proprietary name / brand name	**P-CLAR 125mg Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Suspension Contains: Clarithromycin……..125mg
	Pharmaceutical form of applied drug	Off white to light yellow color flavoured mixed powder.
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Claritek suspension by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Claritek suspension of Getz Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
API Lot No.	CTM0685
Description of Pack (Container closure system)	Glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-13	T-14	T-15
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	23-04-2022	23-04-2022	23-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous approval as it is a new DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delvery challan dated 11-04-2022 for 25 Kg clarithromycin pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	We have used shimadzu HPLC there was a problem in software of attached computer system due to this problem the audit trail couldn't trail couldn't be turned on the whole process of stability study.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The drug substance used in the applied formulation contains clarithromycin granules manufactured by Vision Pharmaceuticals while the drug substance details provided in section 3.2.S.1 is for white to off white crystalline powder. Clarification is required in this regard.	*Before the processing of taste masked granules the specified powder White to off white crystalline powder physically appearance mentioned by API Manufacturer.*
2.	Specify the exact polymorphic form of the drug substance used in this preparation since the public assessment report of reference product specifies that the drug substance exists in multiple polymorphic forms and that only 1 form is active.	**Firm has not submitted any response.**
3.	Justify the use of enteric coated pllets/granules for the development of applied product, since the innovator and reference product does not specify that the innovator product contains enteric coated granules, further the pharmacokinetic profiles and the recommendations of FDA dissolution profile database also confirms that the innovator product does not contain enteric coated granules or gastroresistent pellets.	*DMF of Vision pharmaceuticals is under revision.* **Firm has not submitted any response.**
4.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration	**Firm has again submitted API specifications of Vision pharmaceuticals.**

	Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.	
5.	Justify the drug substance loss on drying (LOD) limit NMT 5% while USP recommends the LOD limit NMT 2%.	*Our product is as per USP while the Taste Masked Granules was non-Compendia as they are use as internal specifications.* **Firm is using pellets having upto 5% loss on drying while USP required the LOD to be less than 2%.**
6.	Provide verification studies of drug substance from drug product manufacturer.	**Firm has submitted one page table in which results of precision is mentioned without any other test, results and protocols.**
7.	Justify the use of dried sugar as sweetner while you are already using taste masked granules of clarithromycin in your formulation.	*Dried sugar is used not only as sweetener, but also as viscosity builder, thickening agent and bacteriostatic / biostatic property.* **Reference product has not used this excipient.**
8.	Justify the use of xanthan gum as thickening agent along with granules in the formulation	*Granules are in suspension form, therefore xanthan gum is used as suspending agent.* **Reference product has not used this excipient.**
9.	Justify how 5.42gm of clarithromycin tast masked granles is equivalent to 125mg clarithromycin.	**Firm has not provided any justification**.
10.	Justify the use of flavour in your formulation while you are already using taste masked granules of clarithromycin.	*To enhance the acceptability of our product, the brand leader name Claritek 125mg/5ml granules for oral suspension. Batch # D02033 has already orange flavour.*
11.	Justify the use of citric acid in your formulation while the pH is already controlled by the drug substance manufacturer at pellets stage and pH test is specified in COA of drug substance.	*As the product is a pharmacopeia we use this buffering agents Ceric Acid to maintain the ph limit in pharmaceutical dosage form.*
12.	Justify the use of aerosol and titanium dioxide in your formulation.	*Our product is as a suspension therefore Aerosol is used for as a flow properties and anticaking agent for powder while titanium dioxide is used for as a colorant agent.* **Reference product has not used this excipient.**
13.	Provide details about the container closure system of your applied formulation along with total volume of the container and total clarithromycin contents per bottle. Since the innovator's product has declared that they are using 1250mg clarithromycin per 50ml bottle and 2500mg clarithromycin per 100ml bottle.	*We are already using clarithromycin as same proportion as innovator, and our pack size is 60ml.* **The innovator's product is available as 50ml and 100ml.**
14.	Justify why the qualitative composition of applied product is different from that of innovator's product.	*Our choice of materials is own this product stable and have me-to status the given active and Inactive materials that were used are compatible, stable chemically and as well as physically during the 6th month performed stability study.* **Firm has not provided any scientific justification or compatibility studies.**
15.	Justify why pharmaceutical equivalence is not performed against the innovator's product.	*Due to non-availability of Innovator's than we use brand leader instead of Innovator.*
16.	Justify why comparative dissolution profile (CDP) studies is not conducted for the applied product since FDA as well as public assessment reports of other reference regulatory authorities specifies that comparative dissolution profile against the innovator's product is required to establish the equivalence and interchangeability of the applied product.	*Our product is as per USP Specification there is no specified the competitive dissolution profile (CDP) in USP specification.* **FDA has given details of dissolution parameters in FDA dissolution database and also provided product specific guidelines or this product.**

17.	Provide preservative effectiveness studies for the applied product.	*We used Sodium Benzoate as a preservative.* **Preservative effectiveness studies are not provided.**
18.	Submit compatibility studies of the applied product along with recommended diluent.	*Our product as per USP pharmacopeia. There was no recommended diluent as per USP therefore we use Water as a diluent and our product is compatible with this diluent.* **Firm has not provided compatibility studies of the applied product along with recommended diluent.**
19.	Provide complete description and details of container closure system of the applied product whether glass bottle or PP bottle etc.	*Existing container closure system is on Amber Glass Bottles with Aluminum Caps. In future we will use commercial batches with proper glass bottles and secondary packaging materials.*
20.	Justify significant change (i.e. more than 5% change in assay result from initial value) from 98.72% to 105.10% in your stability studies result.	*The batches was manufactured as a small scale significant changed was **accrued due to weight variation**, but we made first batches, we used higher capacity machinery for small scale batches.* **Firm has not performed weight variation test throughout the stability studies.**
21.	Submit evidence of HPLC system with column oven having capacity to maintain column temperature at 50°.	Firm has submitted copy of a quotation from Western analytical services dated 22-07-2021for HPLC systm along with column oven.
22.	Submit analytical record of the stability data in a proper sequence as recommended by the Board since you have submitted all raw data sheets together and all chromatograms separately without any sequence and separators to segregate stability data of each batch and each time point.	*We had given complete data , with proper tags were also attached to it, Next time we will use proper separator and we will submit will organize file.* **The submitted data was not organized all chromatograms were submitted together without any segregation which was not possible to be properly evaluated.**

Decision: Approved. Registration letter will be issued upon submission of following:

- **Specifications and analytical method verification studies of drug substance from drug product manufacturer.**
- **Pharmaceutical equivalence and CDP studies with the innovator's product.**
- **Preservative effectiveness studies and compatibility studies with reconstitution diluent for the applied product.**
- **IQ, OQ and PQ report of HPLC system equipped with column oven having capacity to maintain column temperature at 50°C.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1585.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur and Fleming Pharmaceuticals (Pvt) Ltd. Plot No. P.70-A, Road No. 4, Phase-3, Industrial Area Hattar.**
	Name, address of Manufacturing site.	M/s Pasteur and Fleming Pharmaceuticals (Pvt) Ltd. Plot No. P.70-A, Road No. 4, Phase-3, Industrial Area Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000945) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000945) dated 11-11-2021. The letter specifies following section:

		• Tablet (Hormone) • Tablet (General) • Capsule (General) • Dry Powder Suspension (General) • Cream / Ointment Section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27899: 03-10-2022
	Details of fee submitted	PKR 30,000/- : 30-09-2022
	The proposed proprietary name / brand name	**P-CLAR 250mg Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Suspension Contains: Clarithromycin……..250mg
	Pharmaceutical form of applied drug	Off white to light yellow color flavoured mixed powder.
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Claritek suspension by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical

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

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.	CTM0685		
Description of Pack (Container closure system)	Glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-16	T-17	T-18
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	23-04-2022	23-04-2022	23-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous approval as it is a new DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delvery challan dated 11-04-2022 for 25 Kg clarithromycin pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	We have used shimadzu HPLC there was a problem in software of attached computer system due to this problem the audit trail couldn't trail couldn't be turned on the whole process of stability study.

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

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The drug substance used in the applied formulation contains clarithromycin granules manufactured by Vision Pharmaceuticals while the drug substance details provided in section 3.2.S.1 is for white to off white crystalline powder. Clarification is required in this regard.	*Before the processing of taste masked granules the specified powder White to off white crystalline powder physically appearance mentioned by API Manufacturer.*
2.	Specify the exact polymorphic form of the drug substance used in this preparation since the public assessment report of reference product specifies that the drug substance exists in multiple polymorphic forms and that only 1 form is active.	**Firm has not submitted any response.**
3.	Justify the use of enteric coated pllets/granules for the development of applied product, since the innovator and reference product does not specify that the innovator product contains enteric coated granules, further the pharmacokinetic profiles and the recommendations of FDA dissolution profile database also confirms that the innovator product does not contain enteric coated granules or gastroresistent pellets.	*DMF of Vision pharmaceuticals is under revision.* **Firm has not submitted any response.**
4.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.	**Firm has again submitted API specifications of Vision pharmaceuticals.**
5.	Justify the drug substance loss on drying (LOD) limit NMT 5% while USP recommends the LOD limit NMT 2%.	*Our product is as per USP while the Taste Masked Granules was non-Compendia as they are use as internal specifications.* **Firm is using pellets having upto 5% loss on drying while USP required the LOD to be less than 2%.**
6.	Provide verification studies of drug substance from drug product manufacturer.	**Firm has submitted one page table in which results of precision is mentioned without any other test, results and protocols.**
7.	Justify the use of dried sugar as sweetner while you are already using taste masked granules of clarithromycin in your formulation.	*Dried sugar is used not only as sweetener, but also as viscosity builder, thickening agent and bacteriostatic / biostatic property.* **Reference product has not used this excipient.**
8.	Justify the use of xanthan gum as thickening agent along with granules in the formulation	*Granules are in suspension form, therefore xanthan gum is used as suspending agent.* **Reference product has not used this excipient.**
9.	Justify how 5.42gm of clarithromycin tast masked granles is equivalent to 125mg clarithromycin.	**Firm has not provided any justification**.
10.	Justify the use of flavour in your formulation while you are already using taste masked granules of clarithromycin.	*To enhance the acceptability of our product, the brand leader name Claritek 125mg/5ml granules for oral suspension. Batch # D02033 has already orange flavour.*
11.	Justify the use of citric acid in your formulation while the pH is already controlled by the drug substance manufacturer at pellets stage and pH test is specified in COA of drug substance.	*As the product is a pharmacopeia we use this buffering agents Ceric Acid to maintain the ph limit in pharmaceutical dosage form.*

12.	Justify the use of aerosol and titanium dioxide in your formulation.	*Our product is as a suspension therefore Aerosol is used for as a flow properties and anticaking agent for powder while titanium dioxide is used for as a colorant agent.* **Reference product has not used this excipient.**
13.	Provide details about the container closure system of your applied formulation along with total volume of the container and total clarithromycin contents per bottle. Since the innovator's product has declared that they are using 2500mg clarithromycin per 50ml bottle and 5000mg clarithromycin per 100ml bottle.	*We are already using clarithromycin as same proportion as innovator, and our pack size is 60ml.* **The innovator's product is available as 50ml and 100ml.**
14.	Justify why the qualitative composition of applied product is different from that of innovator's product.	*Our choice of materials is own this product stable and have me-to status the given active and Inactive materials that were used are compatible, stable chemically and as well as physically during the 6th month performed stability study.* **Firm has not provided any scientific justification or compatibility studies.**
15.	Justify why pharmaceutical equivalence is not performed against the innovator's product.	*Due to non-availability of Innovator's than we use brand leader instead of Innovator.*
16.	Justify why comparative dissolution profile (CDP) studies is not conducted for the applied product since FDA as well as public assessment reports of other reference regulatory authorities specifies that comparative dissolution profile against the innovator's product is required to establish the equivalence and interchangeability of the applied product.	*Our product is as per USP Specification there is no specified the competitive dissolution profile (CDP) in USP specification.* **FDA has given details of dissolution parameters in FDA dissolution database and also provided product specific guidelines or this product.**
17.	Provide preservative effectiveness studies for the applied product.	*We used Sodium Benzoate as a preservative.* **Preservative effectiveness studies are not provided.**
18.	Submit compatibility studies of the applied product along with recommended diluent.	*Our product as per USP pharmacopeia. There was no recommended diluent as per USP therefore we use Water as a diluent and our product is compatible with this diluent.* **Firm has not provided compatibility studies of the applied product along with recommended diluent.**
19.	Provide complete description and details of container closure system of the applied product whether glass bottle or PP bottle etc.	*Existing container closure system is on Amber Glass Bottles with Aluminum Caps. In future we will use commercial batches with proper glass bottles and secondary packaging materials.*
20.	Justify significant change (i.e. more than 5% change in assay result from initial value) from 99.45% to 105.92% and 100.44% to 106.98% in your stability studies result.	*The batches was manufactured as a small scale significant changed was **accrued due to weight variation**, but we made first batches, we used higher capacity machinery for small scale batches.* **Firm has not performed weight variation test throughout the stability studies.**
21.	Submit evidence of HPLC system with column oven having capacity to maintain column temperature at 50°.	Firm has submitted copy of a quotation from Western analytical services dated 22-07-2021for HPLC systm along with column oven.
22.	Submit analytical record of the stability data in a proper sequence as recommended by the Board since you have submitted all raw data sheets together and all chromatograms separately without any sequence and separators to segregate stability data of each batch and each time point.	*We had given complete data , with proper tags were also attached to it, Next time we will use proper separator and we will submit will organize file.* **The submitted data was not organized all chromatograms were submitted together without any segregation which was not possible to be properly evaluated.**

Decision: Approved. Registration letter will be issued upon submission of following:

- **Specifications and analytical method verification studies of drug substance from drug product manufacturer.**
- **Pharmaceutical equivalence and CDP studies with the innovator's product.**

- **Preservative effectiveness studies and compatibility studies with reconstitution diluent for the applied product.**
- **IQ, OQ and PQ report of HPLC system equipped with column oven having capacity to maintain column temperature at 50°C.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 04: M/s JHK Pharma (Pvt) Ltd. Nowshera.

Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section:

- Intravenous Infusion-LVP (General)
- Intravenous Infusion-LVP (General Antibiotics)

Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections:

- Ampoule-SVP (General)
- Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)

Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	No of molecules	No of products
Intravenous Infusion-LVP (General)	06	14
Liquid Injectable Vial SVP (General)	-	-
Ampoule-SVP (General)	-	-

Intravenous Infusion-LVP (General): 06 Molecules / 14 Products

1586.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30627: 28-10-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL 10% Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…10gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Electrolyte with carbohydrate. ATC code: B05BB02
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Pladex-10 by M/s Otsuka Pakistan Ltd
	Name and address of API manufacturer.	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladex-10 IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China		
API Lot No.	202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 10	Trial # 11	Trial # 12
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	19-04-2022	19-04-2022	19-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170644) issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA

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

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.	Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 10% From glucose monohydrate that means dextrose monohydrate; is utilized by Baxter UK which is same as dextrose anhydrous with one additional molecule of water and approved by US FDA.
2.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
3.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.
5.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
6.	Provide stability study data of drug substance till claimed shelf life since the submitted real time stability data is only for 9 months.	Firm has submitted API stability study data till 24 months as per zone IV-A conditions.
7.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	Firm has submitted verification studies of the analytical method of drug product.
8.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
9.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
10.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
11.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
12.	Describe the minimum and maximum filling capacity of the manufacturing and filling facility.	Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine. No. Made Capacity *Pac* Size *Machine* Machine | Made | Capacity | Pack Size

		simple Cap Welding Machine | ISBM CHINA | 50,000 Bottle/day | 100 mL/ 500mL / 1000mL
13.	Provide raw data sheet for calculation of results of stability studies at each month time point.	Firm has submitted raw data sheets for results of stability studies at each time point.
14.	Submit documents specifying that M/s Atlantic Pharmaceuticals has agreed to give loan of the API for your firm.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**

1587.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP)

		☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30626: 28-10-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL 10% Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…10gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Electrolyte with carbohydrate. ATC code: B05BB02
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Pladex-10 by M/s Otsuka Pakistan Ltd
	Name and address of API manufacturer.	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladex-10 IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China		
API Lot No.	202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 13	Trial # 14	Trial # 15
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	19-04-2022	19-04-2022	19-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170644) issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.	Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 10% From glucose monohydrate that means dextrose monohydrate; is utilized by Baxter UK which is same as dextrose anhydrous with one additional molecule of water and approved by US FDA.
2.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
3.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.
4.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.
5.	Provide COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.
6.	Provide stability study data of drug substance till claimed shelf life since the submitted real time stability data is only for 9 months.	Firm has submitted API stability study data till 24 months as per zone IV-A conditions.
7.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	Firm has submitted verification studies of the analytical method of drug product.
8.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
9.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
10.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
11.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
12.	Describe the minimum and maximum filling capacity of the manufacturing and filling facility.	Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine. No. Made Capacity *Pac* Size *Machine* Machine | Made | Capacity | Pack Size simple Cap Welding Machine | ISBM CHINA | 50,000 Bottle/day | 100 mL/ 500mL / 1000mL

13.	Provide raw data sheet for calculation of results of stability studies at each month time point.	Firm has submitted raw data sheets for results of stability studies at each time point.
14.	Submit documents specifying that M/s Atlantic Pharmaceuticals has agreed to give loan of the API for your firm.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**

1588.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31428: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL 5% Infusion 100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Electrolyte with carbohydrate. ATC code: B05BB02
	Reference to Finished product specifications	BP
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Pladex-5 by M/s Otsuka Pakistan Ltd
	Name and address of API manufacturer.	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product

		against the reference product 'Pladex-5 IV Infusion by M/s Otsuka Pakistan Limited."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China		
API Lot No.	202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170644) issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm

<table>
<tr><td>1.</td><td>Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.</td><td>Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 10% From glucose monohydrate that means dextrose monohydrate; is utilized by Baxter UK which is same as dextrose anhydrous with one additional molecule of water and approved by US FDA.</td></tr>
<tr><td>2.</td><td>Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that “Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required.”</td><td>Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.</td></tr>
<tr><td>3.</td><td>Provide verification studies of drug substance from drug product manufacturer.</td><td>Firm has submitted report of verification studies of the analytical method of drug substance performed by drug product manufacturer.</td></tr>
<tr><td>4.</td><td>Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.</td><td>Firm has submitted COA of batch 202112028 from both API manufacturer as well as drug product manufacturer.</td></tr>
<tr><td>5.</td><td>Provide COA of reference standard actually used in the analysis of drug substance and drug product.</td><td>Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.</td></tr>
<tr><td>6.</td><td>Provide stability study data of drug substance till claimed shelf life since the submitted real time stability data is only for 9 months.</td><td>Firm has submitted API stability study data till 24 months as per zone IV-A conditions.</td></tr>
<tr><td>7.</td><td>Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.</td><td>Firm has submitted verification studies of the analytical method of drug product.</td></tr>
<tr><td>8.</td><td>Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).</td><td>Firm has both facilities of manufacturing the Simple caps & Euro cap.
However the applied product is without Eurocap</td></tr>
<tr><td>9.</td><td>Provide details regarding the method of sterilization of the drug product.</td><td>Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>10.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.</td></tr>
<tr><td>11.</td><td>Submit copy of Batch Manufacturing Record of the stability batches.</td><td>Firm has submitted BMR of three stability batches.</td></tr>
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No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
<tr><td>13.</td><td>Provide raw data sheet for calculation of results of stability studies at each month time point.</td><td>Firm has submitted raw data sheets for results of stability studies at each time point.</td></tr>
</table>

14.	Submit documents specifying that M/s Atlantic Pharmaceuticals has agreed to give loan of the API for your firm.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1589.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 30628: 28-10-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL 5% Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Electrolyte with carbohydrate. ATC code: B05BB02
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Pladex-5 by M/s Otsuka Pakistan Ltd
	Name and address of API manufacturer.	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product 'Pladex-5 IV Infusion by M/s Otsuka Pakistan Limited."

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

STABILITY STUDY DATA

Manufacturer of API	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China		
API Lot No.	202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 4	Trial # 5	Trial # 6
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170644) issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.	Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 10% From glucose monohydrate that means dextrose monohydrate; is

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<tr><td></td><td></td><td>utilized by Baxter UK which is same as dextrose anhydrous with one additional molecule of water and approved by US FDA.</td></tr>
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<tr><td>5.</td><td>Provide COA of reference standard actually used in the analysis of drug substance and drug product.</td><td>Firm has submitted copy of COA of reference standard from the API supplier which was standardized against the BP reference standard.</td></tr>
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However the applied product is without Eurocap</td></tr>
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<tr><td>10.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.</td></tr>
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No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
<tr><td>13.</td><td>Provide raw data sheet for calculation of results of stability studies at each month time point.</td><td>Firm has submitted raw data sheets for results of stability studies at each time point.</td></tr>
<tr><td>14.</td><td>Submit documents specifying that M/s Atlantic Pharmaceuticals has agreed to give loan of the API for your firm.</td><td>Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities:</td></tr>
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		1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**

1590.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30829: 31-10-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL 5% Infusion 1000ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Electrolyte with carbohydrate. ATC code: B05BB02
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Pladex-5 by M/s Otsuka Pakistan Ltd
	Name and address of API manufacturer.	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
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	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance.

		Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China		
API Lot No.	202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 7	Trial # 8	Trial # 9
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. SD20170644) issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
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5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Provide evidence of applied formulation as dextrose anhydrous in reference regulatory authorities.	Dextrose and glucose are used in the same meanings. Baxter UK manufacture glucose 10% From glucose monohydrate that means dextrose monohydrate; is utilized by Baxter UK which is same as dextrose

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<tr><td>14.</td><td>Submit documents specifying that M/s Atlantic Pharmaceuticals has agreed to give loan of the API for your firm.</td><td>Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities:
1. Dextrose Anhydrous 750 KG</td></tr>
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		2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**

1591.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32622: 14-11-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL NS Infusion 100ml**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium Chloride ……..0.9gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Solutions for infusion/electrolytes solution/sodium chloride ATC code: BO5XA03
	Reference to Finished product specifications	USP
	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 0.9% Sodium Chloride Inj. USP, Hospira Inc. Lake Forest USA
	For generic drugs (me-too status)	Zesol-NS Infusion by Shahzaib Pharmaceutical
	Name and address of API manufacturer.	Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for

		their product against 'Zeesol NS Infusion by Shahzaib Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand.		
API Lot No.	**Sodium chloride:** 25052020		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	2000 Bottle	2000 Bottle	2000 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA

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

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.
3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
5.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
6.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
7.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
10.	Submit documents for procurement of all drug substances.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**

• **Firm will submit pharmaceutical equivalence against the innovator's product before issuance of Registration Letter along with fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**		
1592.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32629: 14-11-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL NS Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium Chloride ……..0.9gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	solutions for infusion/electrolytes solution/sodium chloride ATC code: BO5XA03
	Reference to Finished product specifications	USP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 0.9% Sodium Chloride Inj. USP, Hospira Inc. Lake Forest USA
	For generic drugs (me-too status)	Zesol-NS Infusion by Shahzaib Pharmaceutical

	Name and address of API manufacturer.	Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against 'Zeesol NS Infusion by Shahzaib Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand.
API Lot No.	**Sodium chloride:** 25052020
Description of Pack (Container closure system)	LDPE
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	400 Bottle	400 Bottle	400 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.

3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
5.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
6.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
7.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
10.	Submit documents for procurement of all drug substances.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **Firm will submit pharmaceutical equivalence against the innovator's product before issuance of Registration Letter along with fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1593.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947)

		dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32624: 14-11-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL NS Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Sodium Chloride ……..0.9gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	solutions for infusion/electrolytes solution/sodium chloride ATC code: BO5XA03
	Reference to Finished product specifications	USP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 0.9% Sodium Chloride Inj. USP, Hospira Inc. Lake Forest USA
	For generic drugs (me-too status)	Zesol-NS Infusion by Shahzaib Pharmaceutical
	Name and address of API manufacturer.	Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications,

		analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against 'Zeesol NS Infusion by Shahzaib Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand.		
API Lot No.	**Sodium chloride:** 25052020		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	200 Bottle	200 Bottle	200 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.
3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
5.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
6.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
7.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
10.	Submit documents for procurement of all drug substances.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing

		stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **Firm will submit pharmaceutical equivalence against the innovator's product before issuance of Registration Letter along with fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1594.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32817: 15-11-2022

	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL DS Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm Sodium Chloride…..0.9gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Electrolytes with Carbohydrates", ATC code: "B05BB02"
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Pladexsal IV Infusion by M/s Otsuka
	Name and address of API manufacturer.	**Sodium chloride:** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Glucose:** Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Glucose:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against 'Zeesol DS Infusion by Shahzaib Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sodium chloride:** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Glucose:** Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China		
API Lot No.	**Sodium chloride:** 25052020 **Glucose:** 202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	400 Bottle	400 Bottle	400 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023. **Glucose:** Firm has submitted copy of GMP certificate (No. SD20170644) issued by China Food and Drug

		Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium chloride:** Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG **Glucose:** Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.
3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
5.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.

6.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
7.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
10.	Submit documents for procurement of all drug substances.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **Firm will submit pharmaceutical equivalence against the innovator's product before issuance of Registration Letter.**

1595.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections:

		• Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32818: 15-11-2022
	Details of fee submitted	PKR 30,000/- : 25-10-2022
	The proposed proprietary name / brand name	**J-SOL DS Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Glucose anhydrous…5gm Sodium Chloride…..0.9gm
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Electrolytes with Carbohydrates", ATC code: "B05BB02"
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Pladexsal IV Infusion by M/s Otsuka
	Name and address of API manufacturer.	**Sodium chloride:** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Glucose:** Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Glucose:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against 'Zeesol DS Infusion by Shahzaib Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Sodium chloride:** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Glucose:** Xiwang pharmaceutical Co., Ltd. NO.237, Tongfu road, Handian town, Zouping county, Binzhou city, Shandong province, P.R.China		
API Lot No.	**Sodium chloride:** 25052020 **Glucose:** 202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	400 Bottle	400 Bottle	400 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023. **Glucose:** Firm has submitted copy of GMP certificate (No. SD20170644) issued by China Food and Drug Administration. The certificate is valid till 11-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium chloride:** Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG **Glucose:** Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.

2.	Provide verification studies of drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.
3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
5.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
6.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
7.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
10.	Submit documents for procurement of all drug substances.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **Firm will submit pharmaceutical equivalence against the innovator's product before issuance of Registration Letter along with fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1596.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32819: 15-11-2022
	Details of fee submitted	PKR 30,000/- : 14-11-2022
	The proposed proprietary name / brand name	**J-SOL RL Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride dihydrate…… 0.02g Potassium chloride……. 0.03g Sodium chloride……. 0.60g Sodium lactate…… 0.31g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Plasma substitutes and solutions for infusion/electrolytes ATC-Code: B05BB01
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. Lactated Ringer's in Plastic Container by Baxter Healthcare
	For generic drugs (me-too status)	Ringolact injection by Otsuka Pakistan
	Name and address of API manufacturer.	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Calcium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Potassium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Sodium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Sodium lactate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against the reference product 'Ringolact injection by Otsuka
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Calcium chloride:** 200612 **Potassium chloride:** 200414 **Sodium chloride:** 25052020 **Sodium lactate:** 19030660		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	20-04-2022	20-04-2022	20-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Calcium chloride:** Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No. Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025. **Potassium chloride:** Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No.

		Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) of M/s Luoyang Longmen Pharmaceutical Co Ltd issued by NMPA China. The certificate is valid till 29-11-2024. **Sodium chloride:** Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of all drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.
3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
5.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.

6.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
7.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
8.	Describe the minimum and maximum filling capacity of the manufacturing and filling facility.	Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine. No. Made Capacity *Pac* Size *Machine* Machine | Made | Capacity | Pack Size simple Cap Welding Machine | ISBM CHINA | 50,000 Bottle/day | 100 mL/ 500mL / 1000mL
9.	Provide raw data sheet for calculation of results of stability studies based on HPLC testing.	Firm has submitted raw data sheets for results of stability studies at each time point.
10.	Submit documents for procurement of all drug substances.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1597.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32820: 15-11-2022
	Details of fee submitted	PKR 30,000/- : 14-11-2022
	The proposed proprietary name / brand name	**J-SOL RL Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride dihydrate…… 0.02g Potassium chloride……. 0.03g Sodium chloride……. 0.60g Sodium lactate…… 0.31g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	Plasma substitutes and solutions for infusion/electrolytes ATC-Code: B05BB01
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. Lactated Ringer's in Plastic Container by Baxter Healthcare
	For generic drugs (me-too status)	Ringolact injection by Otsuka Pakistan
	Name and address of API manufacturer.	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate**

		Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Calcium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Potassium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Sodium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Sodium lactate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against the reference product 'Ringolact injection by Otsuka
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Calcium chloride:** 200612 **Potassium chloride:** 200414 **Sodium chloride:** 25052020 **Sodium lactate:** 19030660		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 4	Trial # 5	Trial # 6
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	20-04-2022	20-04-2022	20-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Calcium chloride:** Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No. Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025. **Potassium chloride:**

		Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No. Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) of M/s Luoyang Longmen Pharmaceutical Co Ltd issued by NMPA China. The certificate is valid till 29-11-2024. **Sodium chloride:** Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of all drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.
3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap

<table>
<tr><td>5.</td><td>Provide details regarding the method of sterilization of the drug product.</td><td>Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>6.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.</td></tr>
<tr><td>7.</td><td>Submit copy of Batch Manufacturing Record of the stability batches.</td><td>Firm has submitted BMR of three stability batches.</td></tr>
<tr><td>8.</td><td>Describe the minimum and maximum filling capacity of the manufacturing and filling facility.</td><td>Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
<tr><td>9.</td><td>Provide raw data sheet for calculation of results of stability studies based on HPLC testing.</td><td>Firm has submitted raw data sheets for results of stability studies at each time point.</td></tr>
<tr><td>10.</td><td>Submit documents for procurement of all drug substances.</td><td>Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities:
1. Dextrose Anhydrous 750 KG
2. Sodium Chloride 125 Kg
3. Ciprofloxacine Lactate 5 KG
4. Metronidazole 5 KG
5. Levofloxacine 5 KG
6. Paracetamol 10 KG
7. Sodium Lactate 50 KG
8. Potassium Chloride 5 KG
9. Calcium Chloride Dihydrate 5Kg
10. Mannitol 120 KG</td></tr>
</table>

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1598.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections: • Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32821: 15-11-2022
	Details of fee submitted	PKR 30,000/- : 14-11-2022
	The proposed proprietary name / brand name	**J-SOL RLD Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride dihydrate…… 0.02g Potassium chloride……. 0.03g Sodium chloride……. 0.60g Sodium lactate…… 0.31g Dextrose anhydrous…… 5.0g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	B05BB02 "Electrolytes with Carbohydrates".
	Reference to Finished product specifications	USP
	Proposed Pack size	500ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 5% Dextrose in Lactated Ringer's Injection by B. Braun
	For generic drugs (me-too status)	Ringolact-D injection by Otsuka Pakistan
	Name and address of API manufacturer.	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride**

		Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China. **Dextrose** Weifang Shengtai Medicine Co. Ltd. The East of Changda Road, Development District Changle County Weifang City, Shandong Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Calcium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Potassium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Sodium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Sodium lactate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 24 months. **Dextrose** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against the reference product 'Ringolact-D injection by Otsuka
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China. **Dextrose** Weifang Shengtai Medicine Co. Ltd. The East of Changda Road, Development District Changle County Weifang City, Shandong Province China.
API Lot No.	**Calcium chloride:** 200612 **Potassium chloride:** 200414 **Sodium chloride:** 25052020 **Sodium lactate:** 19030660 **Dextrose:** 202106156
Description of Pack (Container closure system)	LDPE
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	21-04-2022	21-04-2022	21-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Calcium chloride:** Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No. Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025. **Potassium chloride:** Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No. Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) of M/s Luoyang Longmen Pharmaceutical Co Ltd issued by NMPA China. The certificate is valid till 29-11-2024. **Sodium chloride:** Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023. **Dextrose:** Firm has submitted copy of GMP certificate (No. SD20180787) of M/s Xiwang pharmaceutical Co., Ltd issued by CFDA China. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG **Dextrose:**

		Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.
2.	Provide verification studies of all drug substance from drug product manufacturer.	Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.
3.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.	Firm has submitted verification studies of the analytical method of drug product.
4.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	Firm has both facilities of manufacturing the Simple caps & Euro cap. However the applied product is without Eurocap
5.	Provide details regarding the method of sterilization of the drug product.	Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.
6.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.
7.	Submit copy of Batch Manufacturing Record of the stability batches.	Firm has submitted BMR of three stability batches.
8.	Describe the minimum and maximum filling capacity of the manufacturing and filling facility.	Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine. No. Made Capacity *Pac* Size *Machine* Machine | Made | Capacity | Pack Size simple Cap | ISBM CHINA | 50,000 Bottle/day | 100 mL/

		Welding Machine | | | 500mL / 1000mL
9.	Provide raw data sheet for calculation of results of stability studies based on HPLC and atomic absorption testing.	Firm has submitted raw data sheets for results of stability studies at each time point.
10.	Submit documents for procurement of all drug substances.	Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities: 1. Dextrose Anhydrous 750 KG 2. Sodium Chloride 125 Kg 3. Ciprofloxacine Lactate 5 KG 4. Metronidazole 5 KG 5. Levofloxacine 5 KG 6. Paracetamol 10 KG 7. Sodium Lactate 50 KG 8. Potassium Chloride 5 KG 9. Calcium Chloride Dihydrate 5Kg 10. Mannitol 120 KG
11.	Submit evidence of purchase of atomic absorption which is required for product testing as per USP monograph.	Firm has submitted copy of invoice No. QCS/MPW321/2022 dated 28-02-2022 from Quality Control Services specifying purchase of refurbished atomic absorption perkin elmer.

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Firm will submit IQ, OQ, PQ for the "Atomic absorption spectrophotometer" before issuance of Registration Letter.**

1599.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.**
	Name, address of Manufacturing site.	M/s JHK Pharma (Pvt) Ltd. Khushal Khan Khattak Mazar Road, Akora Khattak, Nowshera.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000946) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: • Intravenous Infusion-LVP (General) • Intravenous Infusion-LVP (General Antibiotics) Firm has submitted another letter dated 19-05-2022 in which CLB approved grant of following additional sections:

		• Ampoule-SVP (General) • Liquid Injectable Vial SVP (General) in place of Intravenous Infusion-LVP (General/ Antibiotics)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32822: 15-11-2022
	Details of fee submitted	PKR 30,000/- : 14-11-2022
	The proposed proprietary name / brand name	**J-SOL RLD Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride dihydrate…… 0.02g Potassium chloride……. 0.03g Sodium chloride……. 0.60g Sodium lactate…… 0.31g Dextrose anhydrous…… 5.0g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in LDPE bottle
	Pharmacotherapeutic Group of (API)	B05BB02 "Electrolytes with Carbohydrates".
	Reference to Finished product specifications	USP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved. 5% Dextrose in Lactated Ringer's Injection by B. Braun
	For generic drugs (me-too status)	Ringolact-D injection by Otsuka Pakistan
	Name and address of API manufacturer.	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China. **Dextrose** Weifang Shengtai Medicine Co. Ltd. The East of Changda Road, Development District Changle County Weifang City, Shandong Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Calcium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Potassium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 48 months. **Sodium chloride:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. **Sodium lactate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. **Dextrose** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests as per USP for their product against the reference product 'Ringolact-D injection by Otsuka
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Calcium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Potassium chloride** Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China **Sodium chloride** Dominion Salt (NI) Limited, 89 Totara Street Mount Maunganui, New Zealand. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China. **Dextrose** Weifang Shengtai Medicine Co. Ltd. The East of Changda Road, Development District Changle County Weifang City, Shandong Province China.		
API Lot No.	**Calcium chloride:** 200612 **Potassium chloride:** 200414 **Sodium chloride:** 25052020 **Sodium lactate:** 19030660 **Dextrose:** 202106156		
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 4	Trial # 5	Trial # 6
Batch Size	500 Bottle	500 Bottle	500 Bottle
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	21-04-2022	21-04-2022	21-04-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Calcium chloride:** Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No. Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025.

		Potassium chloride: Firm has submitted copy of DML of M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Jiucheng Industrial Park, Hebei, China (Permit No. Hebei 20150116) issued by NMPA China. The license is valid till 11-08-2025. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) of M/s Luoyang Longmen Pharmaceutical Co Ltd issued by NMPA China. The certificate is valid till 29-11-2024. **Sodium chloride:** Firm has submitted copy of GMP certificate (No. TT60-565-16-3) of M/s Dominion Salt (NI) Limited issued by MEDSAFE Newzealand. The certificate is valid till 28-01-2023. **Dextrose:** Firm has submitted copy of GMP certificate (No. SD20180787) of M/s Xiwang pharmaceutical Co., Ltd issued by CFDA China. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Calcium chloride:** **Potassium chloride:** **Sodium lactate:** **Sodium chloride:** **Dextrose:** Firm has submitted that we have taken loan of API from Atlantic Pharmaceuticals. ADC invoice is attached. Firm has submitted ADC attested invoice and clearance certificate specifying import of 48000Kg Dextrose anhydrous by M/s Atlantic Pharmaceuticals. The invoice was cleared by AD (I&E) DRAP dated 24-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted specifications of drug substance from both Drug substance & Drug Product manufacturer.

<table>
<tr><td>2.</td><td>Provide verification studies of all drug substance from drug product manufacturer.</td><td>Firm has submitted report of verification studies of the analytical method of all drug substance performed by drug product manufacturer.</td></tr>
<tr><td>3.</td><td>Provide verification studies of the analytical method of drug product in section 3.2.P.5.3.</td><td>Firm has submitted verification studies of the analytical method of drug product.</td></tr>
<tr><td>4.</td><td>Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).</td><td>Firm has both facilities of manufacturing the Simple caps & Euro cap.
However the applied product is without Eurocap</td></tr>
<tr><td>5.</td><td>Provide details regarding the method of sterilization of the drug product.</td><td>Our Sterilizers/ autoclave are PLC controlled with Automatic additional time selection in Sterilization cycle. Details of sterilization process is provided by firm.</td></tr>
<tr><td>6.</td><td>Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.</td><td>Stability study Performed at 30°C ± 2°C at 65% + 5%RH, and at 40°C + 2°C at 75% + 5%RH additional water loss study was performed as per ICH guidelines and the data for water loss is submitted.</td></tr>
<tr><td>7.</td><td>Submit copy of Batch Manufacturing Record of the stability batches.</td><td>Firm has submitted BMR of three stability batches.</td></tr>
<tr><td>8.</td><td>Describe the minimum and maximum filling capacity of the manufacturing and filling facility.</td><td>Our approved Facilities consist of IV infusion section which includes all volume. Detailed capacity was mentioned in attached list (3.2.A Production Machine List). The details of the simple cap machine are provided below simple cap Machine.
No. Made Capacity Pac Size Machine
<table><tr><td>Machine</td><td>Made</td><td>Capacity</td><td>Pack Size</td></tr><tr><td>simple Cap Welding Machine</td><td>ISBM CHINA</td><td>50,000 Bottle/day</td><td>100 mL/ 500mL / 1000mL</td></tr></table></td></tr>
<tr><td>9.</td><td>Provide raw data sheet for calculation of results of stability studies based on HPLC and atomic absorption testing.</td><td>Firm has submitted raw data sheets for results of stability studies at each time point.</td></tr>
<tr><td>10.</td><td>Submit documents for procurement of all drug substances.</td><td>Firm has submitted a letter from Atlantic pharmaceuticals dated 05-04-2022 for Loan of raw material to M/s JHK Pharmaceuticals for performing stability studies. The letter specifies the following APIs along with their quantities:
1. Dextrose Anhydrous 750 KG
2. Sodium Chloride 125 Kg
3. Ciprofloxacine Lactate 5 KG
4. Metronidazole 5 KG
5. Levofloxacine 5 KG
6. Paracetamol 10 KG
7. Sodium Lactate 50 KG
8. Potassium Chloride 5 KG
9. Calcium Chloride Dihydrate 5Kg
10. Mannitol 120 KG</td></tr>
<tr><td>11.</td><td>Submit evidence of purchase of atomic absorption which is required for product testing as per USP monograph.</td><td>Firm has submitted copy of invoice No. QCS/MPW321/2022 dated 28-02-2022 from Quality Control Services specifying purchase of refurbished atomic absorption perkin elmer.</td></tr>
</table>

Decision: Approved along with primary container closure system as "LDPE bottle without Eurocap."

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

- **Registration letter will be issued after verification of the loan letter by M/s Atlantic pharmaceuticals.**
- **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Firm will submit IQ, OQ, PQ reports for the "atomic absorption spectrophotometer" before issuance of Registration Letter.**

Case No. 05: M/s Wallace Pharma Evolutions, Lahore.

Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section:

- Capsule (Penicillin)
- Oral Dry Powder Suspension (Penicillin)
- Dry Powder Injection (Penicillin)
- Injection (Carbapenem)

Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	No of molecules	No of products
Capsule (Penicillin)	03	03
Oral Dry Powder Suspension (Penicillin)	03	03

Capsule (Penicillin) Section: 03 Molecules / 03 Products

1600.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31998: 07-11-2022
	Details of fee submitted	PKR 30,000/- : 03-11-2022
	The proposed proprietary name / brand name	**CLOXXIN 500mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Cloxacillin (as sodium monohydrate)……..500mg
	Pharmaceutical form of applied drug	hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Anaclosil 500 mg hard capsules **CIMA Spain Approved**
	For generic drugs (me-too status)	Cloxazan 500mg Capsule by Zafa
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against cloxacillin capsule without specifying name of manufacturer and brand name. Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against cloxacillin capsule without specifying name of manufacturer and brand name.

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

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00022/054/2021		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	C-01	C-02	C-03
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	25-02-2022	25-02-2022	25-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Specify whether the drug substance used is in compacted form or micronized.
- Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence and CDP studies have been performed.

• Justify why pharmaceutical equivalence and CDP studies are not performed against innovator / reference product. • Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided. • Provide COA of reference standard / working standard actually used in the analysis of drug product. • Provide description of container closure system whether Alu-Alu blister or otherwise. • Submit copy of invoice for procurement of drug substance from Pharmagen. • Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1601.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31471: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 28-10-2022
	The proposed proprietary name / brand name	**AMPICA 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Ampicillin (as trihydrate)……..500mg
	Pharmaceutical form of applied drug	Gray opaque cap and light blue opaque body hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Penbritin Capsule by GSK

	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Penbritin Capsule of GSK. Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Penbritin Capsule of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	00002/012/2022
Description of Pack (Container closure system)	Alu-Alu Blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-01	A-02	A-03
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Specify whether the drug substance used is in compacted form or micronized.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided.
- Submit evidence of automatic analyzer equipped with spectrophotometer having analysis capability at 480 nm.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Provide description of container closure system whether Alu-Alu blister or otherwise.
- USP monograph specifies Iodometric Assay specified in USP general chapter <425> while in stability studies and analytical method verification you have used HPLC method for assay testing. Clarification is required in this regard.
- Justify how the dissolution testing performed in stability studies is according to the method specified in USP monograph.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1602.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31472: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 28-10-2022
	The proposed proprietary name / brand name	**AMOXACE 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Amoxicillin (as trihydrate)……..500mg
	Pharmaceutical form of applied drug	Blue opaque cap and pink opaque body hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Amoxil Capsule by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Amoxil Capsule of GSK. Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Amoxil Capsule of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	000130/0047/2022		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-01	A-02	A-03
Batch Size	1500 Capsule	1500 Capsule	1500 Capsule
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	22-02-2022	22-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since only a single table result is provided.
- Justify why microbial enumeration test is not performed at the batch analysis and batch release stage as evident from the batch release certificate provided in section 3.2.P.5.4.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

Oral Dry Powder Suspension (Penicillin): 03 Molecules / 03 Products		
1603.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin)

		• Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31473: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 28-10-2022
	The proposed proprietary name / brand name	**AMOXACE 125mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Amoxicillin (as trihydrate)……..125mg
	Pharmaceutical form of applied drug	White to yellowish color powder in the suspension bottle
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Amoxil suspension by GSK
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product,

		specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the reference product Amoxil suspension of GSK.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	000130/0047/2022		
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-04	A-05	A-06
Batch Size	120 Bottles	120 Bottles	120 Bottles
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	22-02-2022	22-02-2022	22-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine

testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.

- Provide verification studies of drug substance from drug product manufacturer.
- Justify the use of amoxicillin trihydrate compacted API for manufacturing of suspension, since the reference product reveals that micronized particle size is required to achieve the desired drug contents after reconstitution.
- Justify why the qualitative composition is different from that of the innovator's product.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since FDA dissolution method have recommended dissolution parameters for the applied product.
- Provide preservative effectiveness studies for the drug product in section 3.2.P.2.5.
- Provide compatibility studies of the product along with recommended diluent in section 3.2.P.2.6.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Provide details of the container closure system of the applied product whether packed in glass bottle or PET bottle along with the color of the bottle.
- Justify how 120 bottles batch size is sufficient enough to complete the stability studies.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

1604.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31474: 02-11-2022
	Details of fee submitted	PKR 30,000/- : 28-10-2022
	The proposed proprietary name / brand name	**AMPICA 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Ampicillin (as trihydrate)……..250mg
	Pharmaceutical form of applied drug	White to yellowish color powder in the suspension bottle

	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Ampcigen suspension by Genera
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against ampicillin suspension without specifying the name of manufacturer or brand name.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	00002/012/2022
Description of Pack	

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-04	A-05	A-06
Batch Size	120 Bottles	120 Bottles	120 Bottles
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Specify whether the drug substance used is in compacted form or micronized.
- Justify why the qualitative composition is different from that of the innovator's product.
- Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence studies have been performed.
- Justify why pharmaceutical equivalence studies are not performed against innovator / reference product.
- Provide results of comparative dissolution profile (CDP) in three dissolution medium since FDA dissolution method have recommended dissolution parameters for the applied product.
- Provide preservative effectiveness studies for the drug product in section 3.2.P.2.5.
- Provide compatibility studies of the product along with recommended diluent in section 3.2.P.2.6.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Provide details of the container closure system of the applied product whether packed in glass bottle or PET bottle along with the color of the bottle.
- Justify how 120 bottles batch size is sufficient enough to complete the stability studies.

• USP monograph specifies Iodometric Assay specified in USP general chapter <425> while in stability studies and analytical method verification you have used HPLC method for assay testing. Clarification is required in this regard. • Submit copy of invoice for procurement of drug substance from Pharmagen. • Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1605.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site	M/s Wallace Pharma Evolutions, Kalalwala Stop, 20-Km, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000951) dated 27-12-2021. The letter specifies following section: • Capsule (Penicillin) • Oral Dry Powder Suspension (Penicillin) • Dry Powder Injection (Penicillin) • Injection (Carbapenem)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32000: 07-11-2022
	Details of fee submitted	PKR 30,000/- : 03-11-2022
	The proposed proprietary name / brand name	**CLOXXIN 250mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Cloxacillin (as sodium monohydrate)……..250mg
	Pharmaceutical form of applied drug	White to yellowish color powder in the suspension bottle
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Could not be confirmed**
	For generic drugs (me-too status)	Cloxazan suspension 250mg by Zafa
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information

		related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data is conducted till 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against cloxacillin suspension without specifying the name of manufacturer or brand name.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00022/054/2021		
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	A-04	A-05	A-06
Batch Size	120 Bottles	120 Bottles	120 Bottles
Manufacturing Date	02-2022	02-2022	02-2022

Date of Initiation	25-02-2022	25-02-2022	25-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Specify whether the drug substance used is in compacted form or micronized.
- Justify why the qualitative composition is different from that of the innovator's product.
- Provide details including name of manufacturer, expiry date and batch number of the comparator product against which pharmaceutical equivalence studies have been performed.
- Justify why pharmaceutical equivalence studies are not performed against innovator / reference product.
- Provide preservative effectiveness studies for the drug product in section 3.2.P.2.5.
- Provide compatibility studies of the product along with recommended diluent in section 3.2.P.2.6.
- Provide COA of reference standard / working standard actually used in the analysis of drug product.
- Provide details of the container closure system of the applied product whether packed in glass bottle or PET bottle along with the color of the bottle.
- Justify how 120 bottles batch size is sufficient enough to complete the stability studies.
- Submit copy of invoice for procurement of drug substance from Pharmagen.
- Provide Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

b. Deferred Cases

1606.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9889: 30-03-2021
	Details of fee submitted	PKR 20,000/-: 09-03-2021
	The proposed proprietary name / brand name	**GEN-ONE 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…250mg

Remarks of evaluator[3]:

Shortcomings communicated	**Response by the firm**
Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	Firm has submitted that the brand leader of the product Velosef injection is being manufactured and marketed by GSK in Pakistan. All these strengths i.e. 250mg, 500mg and 1gm are registered and readily being sold in Pakistan.

Decision of 312th meeting of Registration Board:

Deferred for following submissions:

- Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
- Submission of fee since the title of the firm has been changed from Biogen Pharmaceuticals to Biogen Life sciences.

Response by the firm:

Firm has submitted its response in which the decision of 320th meeting of Registration Board is referred. The decision is as under:

Registration Board deliberated the matter in detail and acknowlwdged the fact that the "Cephradien injection" has not been withdrawan from US market due to safety & efficacy reasons as evident from the above cited notice published in US Federal Register. Hence, Registration Board decided to consider pending registration applications in the light of aforementioned position.

Based on the decision of 320th meeting of RB, firm has requested to consider their case. The detailed evaluation summary of the case is as under:

Name, address of Applicant / Mar keting Authorization Holder	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Status of the applicant	☒ Manufacturer ☐ Importer

	☐ Is involved in none of the above (contract giver)
GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin).
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 9889: 30-03-2021
Details of fee submitted	PKR 20,000/-: 09-03-2021
The proposed proprietary name / brand name	**GEN-ONE 250mg Injection**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…250mg
Pharmaceutical form of applied drug	Powder for solution for injection
Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
Reference to Finished product specifications	USP
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	NA
For generic drugs (me-too status)	Velosef Injection by GSK
Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co., Ltd No. 98 Hainan Road, Economic and Technological Development Zone, Shijiazhuang, Hebei Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real

	time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 18 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Velosef Injection of GSK.
Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co., Ltd No. 98 Hainan Road, Economic and Technological Development Zone, Shijiazhuang, Hebei Province, China.		
API Lot No.	B2171911012		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-073	T-074	T-075
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	02-06-2020	02-06-2020	02-06-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20180086) issued by CFDA China. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Each vial contains: Cephradine ……250 mg (As cephradine with L-arginine).
2.	Specify whether the drug substance is cephradine or cephradine monohydrate.	The drug substance is Cephradine L-Arginine
3.	Justify your master formulation which specifies cephradine L-arginine, while the drug substance is cephradine / cephradine monohydrate along with L-arginine.	Cephradine L-Arginine equivalent to Cephradine
4.	Submit documents for the procurement of API with approval from DRAP.	Firm has submitted DHL receipt in name of M.s Biogen pharmaceuticals, declarinig the shipment details for "Cephradine sterile with L-Arginine" dated 18-05-2020
5.	Submit batch manufacturing record of three stability batches.	Firm has submitted copy of BMR of three stability batches
6.	Submit fee since the title of the applicant firm has been changed.	Firm has not submitted any fee.

Decision: Approved.

- **Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**
- **Firm shall submit fee of Rs. 30,000 since the title of the firm has been changed from Biogen Pharmaceuticals to Biogen Life Sciences, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of registration letter.**
- **Registration Board further directed the firm to get formal approval for import of drug substance form DRAP I&E office in future.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1607.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9890: 30-03-2021
	Details of fee submitted	PKR 20,000/-: 09-03-2021
	The proposed proprietary name / brand name	**GEN-ONE 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…500mg
	Remarks of evaluator[3]:	

Shortcomings communicated	**Response by the firm**
Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	Firm has submitted that the brand leader of the product Velosef injection is being manufactured and marketed by GSK in Pakistan. All these strengths i.e. 250mg, 500mg and 1gm are registered and readily being sold in Pakistan.

Decision of 312th meeting of Registration Board:
Deferred for following submissions:

- Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
- Submission of fee since the title of the firm has been changed from Biogen Pharmaceuticals to Biogen Life sciences.

Response by the firm:
Firm has submitted its response in which the decision of 320th meeting of Registration Board is referred. The decision is as under:
Registration Board deliberated the matter in detail and acknowlwdged the fact that the "Cephradien injection" has not been withdrawan from US market due to safety & efficacy reasons as evident from the above cited notice published in US Federal Register. Hence, Registration Board decided to consider pending registration applications in the light of aforementioned position.
Based on the decision of 320th meeting of RB, firm has requested to consider their case. The detailed evaluation summary of the case is as under:

Name, address of Applicant / Mar keting Authorization Holder	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin).
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 9890: 30-03-2021
Details of fee submitted	PKR 20,000/-: 09-03-2021
The proposed proprietary name / brand name	**GEN-ONE 500mg Injection**

Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…500mg
Pharmaceutical form of applied drug	Powder for solution for injection
Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
Reference to Finished product specifications	USP
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	NA
For generic drugs (me-too status)	Velosef Injection by GSK
Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co., Ltd No. 98 Hainan Road, Economic and Technological Development Zone, Shijiazhuang, Hebei Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Velosef Injection of GSK.
Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co., Ltd No. 98 Hainan Road, Economic and Technological Development Zone, Shijiazhuang, Hebei Province, China.		
API Lot No.	B2171911012		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-076	T-077	T-078
Batch Size	500 vials	500 vials	500 vials
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	02-06-2020	02-06-2020	02-06-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20180086) issued by CFDA China. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Each vial contains: Cephradine ……500 mg (As cephradine with L-arginine).
2.	Specify whether the drug substance is cephradine or cephradine monohydrate.	The drug substance is Cephradine L-Arginine
3.	Justify your master formulation which specifies cephradine L-arginine, while the drug substance is cephradine / cephradine monohydrate along with L-arginine.	Cephradine L-Arginine equivalent to Cephradine
4.	Submit documents for the procurement of API with approval from DRAP.	Firm has submitted DHL receipt in name of M.s Biogen pharmaceuticals, declarinig the shipment

		details for "Cephradine sterile with L-Arginine" dated 18-05-2020
5.	Submit batch manufacturing record of three stability batches.	Firm has submitted copy of BMR of three stability batches
6.	Submit fee since the title of the applicant firm has been changed.	Firm has not submitted any fee.

Decision: Approved.

- **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**
- **Firm shall submit fee of Rs. 30,000 since the title of the firm has been changed from Biogen Pharmaceuticals to Biogen Life Sciences, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration Letter.**
- **Registration Board further directed the firm to get formal approval for import of drug substance form DRAP I&E office in future.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1608.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9888: 30-03-2021
	Details of fee submitted	PKR 20,000/-: 09-03-2021
	The proposed proprietary name / brand name	**GEN-ONE 1g Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…1g

Remarks of evaluator[3]:

Shortcomings communicated	**Response by the firm**
Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	Firm has submitted that the brand leader of the product Velosef injection is being manufactured and marketed by GSK in Pakistan. All these strengths i.e. 250mg, 500mg and 1gm are registered and readily being sold in Pakistan.

Decision of 312th meeting of Registration Board:
Deferred for following submissions:

	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • Submission of fee since the title of the firm has been changed from Biogen Pharmaceuticals to Biogen Life sciences.

Response by the firm:
Firm has submitted its response in which the decision of 320th meeting of Registration Board is referred. The decision is as under:
Registration Board deliberated the matter in detail and acknowlwdged the fact that the "Cephradien injection" has not been withdrawan from US market due to safety & efficacy reasons as evident from the above cited notice published in US Federal Register. Hence, Registration Board decided to consider pending registration applications in the light of aforementioned position.
Based on the decision of 320th meeting of RB, firm has requested to consider their case. The detailed evaluation summary of the case is as under:

Name, address of Applicant / Mar keting Authorization Holder	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies Dry Vial section (Cephalosporin).
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 9889: 30-03-2021
Details of fee submitted	PKR 20,000/-: 09-03-2021
The proposed proprietary name / brand name	**GEN-ONE 1g Injection**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cephradine L-Arginine…1g
Pharmaceutical form of applied drug	Powder for solution for injection
Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
Reference to Finished product specifications	USP
Proposed Pack size	1's
Proposed unit price	As per SRO
The status in reference regulatory authorities	NA
For generic drugs (me-too status)	Velosef Injection by GSK
Name and address of API manufacturer.	M/s NCPC Hebei Huamin Pharmaceutical Co., Ltd No. 98 Hainan Road, Economic and Technological Development Zone, Shijiazhuang, Hebei Province, China.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties,

	solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 18 months.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Velosef Injection of GSK.
Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s NCPC Hebei Huamin Pharmaceutical Co., Ltd No. 98 Hainan Road, Economic and Technological Development Zone, Shijiazhuang, Hebei Province, China.		
API Lot No.	B2171911012		
Description of Pack (Container closure system)	Glass vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-091	T-092	T-093
Batch Size	500 vials	500 vials	500 vials

Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	02-06-2020	02-06-2020	02-06-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. HE20180086) issued by CFDA China. The certificate is valid till 14-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit label claim of applied product in line with the reference product along with submission of requiste fee.	Each vial contains: Cephradine ……1g (As cephradine with L-arginine).
2.	Specify whether the drug substance is cephradine or cephradine monohydrate.	The drug substance is Cephradine L-Arginine
3.	Justify your master formulation which specifies cephradine L-arginine, while the drug substance is cephradine / cephradine monohydrate along with L-arginine.	Cephradine L-Arginine equivalent to Cephradine
4.	Submit documents for the procurement of API with approval from DRAP.	Firm has submitted DHL receipt in name of M.s Biogen pharmaceuticals, declarinig the shipment details for "Cephradine sterile with L-Arginine" dated 18-05-2020
5.	Submit batch manufacturing record of three stability batches.	Firm has submitted copy of BMR of three stability batches
6.	Submit fee since the title of the applicant firm has been changed.	Firm has not submitted any fee.

Decision: Approved.

- **Firm will revise the label claim as per the decision taken by the Boad in instant meeting regarding Cephradine for Injection along with submission of requisite fee for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021**
- **Firm shall submit fee of Rs. 30,000 since the title of the firm has been changed from Biogen Pharmaceuticals to Biogen Life Sciences, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 before issuance of Registration Letter.**
- **Registration Board further directed the firm to get formal approval for import of drug substance form DRAP I&E office in future.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 01: M/s Wezen Pharmaceuticals, Rawat (New / Additional Section)

M/s Wezen Pharmaceuticals, Rawat has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections.

- Tablet (General)
- Capsule (General)
- Sachet (General)
- Oinment / Cream / Gel (General)

Now the firm has submitted following applications as per the details mentioned in the table below:

Name of Section	Previously considered		Freshly applied	
	No of molecules	No of products	No of molecules	No of products
Capsule (General)	03	08	01	02

Capsule (General) Section: 01 Molecule / 02 Product

1609.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections. • Tablet (General) • Capsule (General) • Sachet (General) • Oinment / Cream / Gel (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7362: 16-03-2022
	Details of fee submitted	PKR 30,000/-: 14-01-2022
	The proposed proprietary name / brand name	**DEXZEN 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….30mg
	Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant capsule **USFDA** Approved

	For generic drugs (me-too status)	Razodex Capsule by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
API Lot No.	
Description of Pack (Container closure system)	Alu-alu blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-01
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

- GMP certificate / inspection report of the firm conducted within a period of last three years.
- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any method and procedures for preparation of each type of solution. Furthermore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product, since you have submitted COA of multiple irrelevant batches in this section.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.

- Section 3.2.S.6 specifies that the API manufacturer is using food grade double polyethylene bag for storing these pellets which are highly sensitive to moisture and light. Justification is required in this regard.
- Provide information in section 3.2.S.7.1 amd 3.2.S.7.2 as per CTD guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.
- The stability study of dexlansoprazole pellets performed by Vision Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.
- Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of dexlansoprazole pellets wherein the representative from the pellets manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarification is required in this regard.
- Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.
- Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be perfomed, since you have mentioned that pharmaceutical equivaelence is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not performed.
- Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter.
- Submit information in section 3.2.P.3 as per the guidance document which specifies that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified".
- Provide information in section 3.2.P.3.2 as per the CTD guidance document which specifies that "A batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards, since you have only submitted the same table which is already provided in section 3.2.P.1.
- Provide information in section 3.2.P.3.3 as per the CTD guidance document which specifies that "A flow diagram shall be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted shall be identified. Proposals for the reprocessing of materials (if any) shall be justified. Any data to support this justification shall be provided in this section. The maximum holding time for bulk product prior to final packaging shall be stated. The holding time shall be supported by the submission of stability data if longer than 30 days. For an aseptically processed drug product, sterile filtration of the bulk and filling into final containers shall preferably be continuous; any holding time shall be justified".
- Provide information in section 3.2.P.3.4 as per the CTD guidance document which specifies that "Tests and acceptance criteria shall be provided (with justification, including experimental data) performed at the critical steps identified in 3.2.P.3.3 of the manufacturing process, to ensure that the process is controlled."
- Justify why the process validation protocols does not include any step for validation of process of capsule filling, sealing and blistering. Moreover, no critical steps, sampling plan, and evaluation criteria has been established.
- Provide specifications of the drug product in section 3.2.P.5.1 along with submission of fee for revision of specifications since you have submitted Vision pharmaceuticals specifications of pellets in this section.
- Provide complete and analytical procedures of drug product in section 3.2.P.5.2 since you have provided analytical procedures of pellets in this section. Moreover, in assay test you have mentioned both UV and HPLC test. Clarification is required in this regard.
- Provide validation studies of the analytical method of drug product in section 3.2.P.5.3.

- Provide batch analysis certificate of three batches of drug product in section 3.2.P.5.4 where you have provided COA of dexlansoprazole pellets of Vision Pharmaceuticals with same results and your signatures after removing header containing name of Vision Pharmaceuticals.
- Provide COA of the reference standard / working standard in section 3.2.P.6 which is actually used in the analysis of drug product along with its standardization record with the primary standard.
- Provide information in section 3.2.P.7 as per the CTD guidance document which specifies that "A detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided."
- You have mentioned white to off white pellets in section 3.2.P.1 while white and green pellets in section 3.2.P.8.1. Justification is required in this regard.
- Provide information in section 3.2.P.8.1 and 3.2.P.8.2 as per the Form 5F and CTD guidance document, since you have skipped these two sections and did not provide any information in these sections.
- Justify why only assay and dissolution test at one medium is performed in stability studies as evident from the submitted stability summary sheets.
- Your drug product specifications submitted in section 3.2.P.5.1 and specifications mentioned in COA of stability studies are different specifically in terms of dissolution test. Justify how you have performed stability studies without having any clear written specifications and analytical method.
- Justify the dissolution test in which the acceptance criteria is NLT 75% in 5 hours which is against the specificatiosn of innovator's product.
- Justify the dissolution acceptance criteria without specifying the value of Q as well as without identifying the criteria for analysis of results of dissolution test as per the criteria defined in USP general chapter <711> as well as defined by Registration Board in its 293rd meeting.
- Provide complete results of dissolution test including result of individual unit of capsule in the summary sheet or COA since results cannot be analysed without having results of individual units of the capsule.
- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

1610.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23 & 24, S-1, RCCI Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	

	Evidence of approval of manufacturing facility	has submitted copy of letter of grant of additional section dated 30-12-2020 for following 4 sections. • Tablet (General) • Capsule (General) • Sachet (General) • Oinment / Cream / Gel (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7363: 16-03-2022
	Details of fee submitted	PKR 30,000/-: 14-01-2022
	The proposed proprietary name / brand name	**DEXZEN 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….60mg
	Pharmaceutical form of applied drug	Small white round enteric coated pellets encapsulated in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant capsule **USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz Pharma
	Name and address of API manufacturer.	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.		
API Lot No.			
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	1200 Capsule	1200 Capsule	1200 Capsule
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	27-02-2021	27-02-2021	27-02-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad dated 31-07-2019. The GMP certificate was granted based on inspection dated 11-02-2019. The GMP certificate is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 23-02-2021 specifying purchase of 2Kg dexlansoprazole pellets 22.5%.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm submitted that their HPLC system is not 21 CFR compliant therefore the audit trail reports are not applicable.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC[3]:

- GMP certificate / inspection report of the firm conducted within a period of last three years.
- Provide Quality Overall Summary in module 2 as per WHO QOS PD template or as per the template defined by Registration Board by providing summarized data in the tabulated form. You have submitted same data of module 3 in QOS as well which is not in line with the CTD guidance document.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Provide complete report of verification studies of the analytical method of drug substance performed by drug product manufacturer in section 3.2.S.4.3, since you have only submitted tabulated results without any method and procedures for preparation of each type of solution. Furthermore, you have performed 6 replicates in specificity test which is not in line with the recommendations of ICH.
- Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product, since you have submitted COA of multiple irrelevant batches in this section.
- Provide COA of the reference standard / working standard in section 3.2.S.5 which is actually used in the analysis of drug substance / pellets along with its standardization record with the primary standard, since you have submitted COA of batch No WS/RLP/01 from Integrin Life Sciences whose product description is different from that specified in section 3.2.S.1 of your application and is neither the manufacturer of these pellets or any other source of reference standard manufacturing.
- Section 3.2.S.6 specifies that the API manufacturer is using food grade double polyethylene bag for storing these pellets which are highly sensitive to moisture and light. Justification is required in this regard.
- Provide information in section 3.2.S.7.1 amd 3.2.S.7.2 as per CTD guidance document since you have only submitted stability data sheets in section 3.2.S.7 which is not in line with the Form 5-F as well as CTD guidance document.
- The stability study of dexlansoprazole pellets performed by Vision Pharmaceuticals specify that the pellets were stored in PET sealed bottles during stability studies while as per section 3.2.S.6 the packaging material of commercially manufactured pellets is food grade double polyethylene bag. Justify how these stability studies are applicable in this case and how it represents the true shelf life of the commercially manufactured pellets.
- Registration Board in its 276th meeting held on 22-25th November, 2017 reviewed the formulation of dexlansoprazole pellets wherein the representative from the pellets manufacturer appeared before the Board and admitted that previously they were not specifying testing of pellets at 5.5 pH in the COA. The submitted stability study data of the three batches of pellets manufactured in 2014 is submitted in which testing at pH 5.5 is also specified. Clarification is required in this regard.
- Submit complete information in section 3.2.P.1 as per form 5F without skipping any section or heading.
- Submit pharmaceutical equivalence report of the applied product along with reference / innovator's product in which all tests as per specifications shall be perfomed, since you have mentioned that pharmaceutical equivaelence is not required and then you have also provided a brief report of dexlansoprazole tablet in which all tests are not performed.
- Provide complete report of comparative dissolution profile along with test parameters, analytical method and how the results are obtained and analysed, since you have only submitted tabulated and graphical representation without specifying any parameter.
- Submit information in section 3.2.P.3 as per the guidance document which specifies that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its

critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified".

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

- Provide stability study data in a proper sequence by providing stability summary sheet of individual batch along with proper separators to provide COA / raw data sheets along with HPLC chromatograms of standard and sample for the particular time point of that batch. Your submitted data is without any sequence, you have provided all COA and raw data sheets together and the rest of the data is also provided without proper sequence and sperators as per the guidelines of Registration Board. Submit your aligned data in a sequence so that further evaluation may be carried out.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.

On the recommendations of panel of experts, the CLB in its 277th meeting held on 15th -16th October has considered and approved the following one additional section of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. The details of the products applied and already considered against new section are as under:

Already considered in 297th meeting		Freshly applied	
Molecules	Products	Molecules	Products
03	05	01	03

Dry Powder Inhalers Section (General) (1 molecules / 3 Product)

1611.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued based on the inspection dated 7th May 2019. Firm has submitted copy of GMP inspection report dated 20-10-2021 concluding that the firm is operating at good level of GMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 27-10-2020 specifying Dry Powder Inhaler Capsule (General) - New section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 17608: 16-06-2022
	Details of fee submitted	PKR 75,000/-: 25-05-2022
	The proposed proprietary name / brand name	**INDACTURA DPI Capsules 150mcg + 80mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Indacaterol (as Acetate)……150 mcg Mometasone Furoate…….80 mcg Each delivered dose contains: Indacaterol (as Acetate)……125 mcg Mometasone Furoate…….62.5 mcg
	Pharmaceutical form of applied drug	Rotacaps
	Pharmacotherapeutic Group of (API)	LABAs and Inhaled synthetic corticosteroid
	Reference to Finished product specifications	In house
	Proposed Pack size	10's, 30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Atectura Breezhaler by Novartis Europharm Limited **EMA** Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Indacaterol Acetate:** Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Dist - Thane-Zone 4, Maharashtra State, India. **Mometasone Furoate:** Aarti Industries Limited Plot No E-50, MIDC, Tarapur, Taluka & District-Palghar, 401506 Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Indacaterol acetate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months.

		Mometasone Furoate: Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Atectura 150/80mcg DPI capsule (Batch No BWK15) Novartis. Firm has also submitted results of invitro comparative delivered dose uniformity and aerodynamic particle size distribution for their product against the Atectura 150/80mcg DPI capsule of Novartis
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Indacaterol Acetate:** Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Dist - Thane- Zone 4, Maharashtra State, India. **Mometasone Furoate:** Aarti Industries Limited Plot No E-50, MIDC, Tarapur, Taluka & District-Palghar, 401506 Maharashtra State, India.		
API Lot No.	**Indacaterol acetate:** ICA/08/21 **Mometasone Furoate:** MF-20016(JM-01)-001		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-1824-S	NPD-C-1825-S	NPD-C-1826-S
Batch Size	6000 capsule	6000 capsule	6000 capsule
Manufacturing Date	01-2022	01-2022	01-2020
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empator 10mg Tablets" which was presented in 291st meeting of Registration Board wherein the Board decided to approve registration of this product Date of inspection: 6th August, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Indacaterol acetate:** Firm has submitted copy of GMP certificate (No. 6100560) dated 09-07-2021 issued by FDA Mahrashtra. The certificate is valid till 08-07-2022. Firm has also submitted copy of Form 29 License to manufacture drugs for purposes of examination, test or analysis (Test Licence No: 201525228 dated 05-01-2021 valid till 04-01-2024. **Mometasone Furoate:** Firm has submitted copy of GMP certificate (No. 92338/2020/11/32133) dated 10-06-2020 issued by FDA Mahrashtra. The certificate is valid till 09-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Indacaterol acetate:** Firm has submitted copy of commercial invoice cleared dated 30-08-2021 specifying import of 40g Indacaterol acetate. The commercial invoice is attested by AD (I&E) DRAP field office. **Mometasone Furoate:** Firm has submitted copy of commercial invoice cleared dated 14-07-2021 specifying import of 0.040Kg Mometasone Furoate. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

DPI device: Monodose Inhaler RS01 Mod. 7 (Catalogue Code: "239700001AB")
Manufacturer: Berry Plastiape S.p.A

Sr. No	Shortcomings communicated	Response by the firm
1.	API stability study data of Indacaterol acetate is till 12 months only.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months.
2.	Further justify how drug substance was procured from a manufacturer which holds Licence to manufacture drugs for purposes of examination, test or analysis.	Firm has submitted copy of License Retention dated 09-05-2022 issued by FDA Mahrashtra State valid till 24-05-2027.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter:**

"DPI device: Monodose Inhaler RS01 Mod. 7 (Catalogue Code: "239700001AB")
Manufacturer: Berry Plastiape S.p.A"

1612.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued based on the inspection dated 7th May 2019. Firm has submitted copy of GMP inspection report dated 20-10-2021 concluding that the firm is operating at good level of GMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 27-10-2020 specifying Dry Powder Inhaler Capsule (General) - New section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17861: 20-06-2022
	Details of fee submitted	PKR 75,000/-: 25-05-2022
	The proposed proprietary name / brand name	**INDACTURA DPI Capsules 150mcg + 160mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Indacaterol (as Acetate)……150 mcg Mometasone Furoate…….160 mcg Each delivered dose contains: Indacaterol (as Acetate)……125 mcg Mometasone Furoate…….127.5 mcg
	Pharmaceutical form of applied drug	Rotacaps
	Pharmacotherapeutic Group of (API)	LABAs and Inhaled synthetic corticosteroid
	Reference to Finished product specifications	In house
	Proposed Pack size	10's, 30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Atectura Breezhaler by Novartis Europharm Limited **EMA** Approved.

	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Indacaterol Acetate:** Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Dist - Thane- Zone 4, Maharashtra State, India. **Mometasone Furoate:** Aarti Industries Limited Plot No E-50, MIDC, Tarapur, Taluka & District-Palghar, 401506 Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Indacaterol acetate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months. **Mometasone Furoate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Atectura 150/160mcg DPI capsule (Batch No BUE50) of Novartis.

		Firm has also submitted results of invitro comparative delivered dose uniformity and aerodynamic particle size distribution for their product against the Atectura 150/160mcg DPI capsule of Novartis
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Indacaterol Acetate:** Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Dist - Thane- Zone 4, Maharashtra State, India. **Mometasone Furoate:** Aarti Industries Limited Plot No E-50, MIDC, Tarapur, Taluka & District-Palghar, 401506 Maharashtra State, India.		
API Lot No.	**Indacaterol acetate:** ICA/08/21 **Mometasone Furoate:** MF-20016(JM-01)-001		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-1829-S	NPD-C-1830-S	NPD-C-1831-S
Batch Size	6000 capsule	6000 capsule	6000 capsule
Manufacturing Date	01-2022	01-2022	01-2020
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empator 10mg Tablets" which was presented in 291st meeting of Registration Board wherein the Board decided to approve registration of this product Date of inspection: 6th August, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Indacaterol acetate:** Firm has submitted copy of GMP certificate (No. 6100560) dated 09-07-2021 issued by FDA Mahrashtra. The certificate is valid till 08-07-2022. Firm has also submitted copy of Form 29 License to manufacture drugs for purposes of examination, test or analysis (Test Licence No: 201525228 dated 05-01-2021 valid till 04-01-2024. **Mometasone Furoate:** Firm has submitted copy of GMP certificate (No. 92338/2020/11/32133) dated

		10-06-2020 issued by FDA Mahrashtra. The certificate is valid till 09-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Indacaterol acetate:** Firm has submitted copy of commercial invoice cleared dated 30-08-2021 specifying import of 40g Indacaterol acetate. The commercial invoice is attested by AD (I&E) DRAP field office. **Mometasone Furoate:** Firm has submitted copy of commercial invoice cleared dated 14-07-2021 specifying import of 0.040Kg Mometasone Furoate. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

DPI device: Monodose Inhaler RS01 Mod. 7 (Catalogue Code: "239700001AB")
Manufacturer: Berry Plastiape S.p.A

Sr. No	Shortcomings communicated	Response by the firm
1.	API stability study data of Indacaterol acetate is till 12 months only.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months.
2.	Further justify how drug substance was procured from a manufacturer which holds Licence to manufacture drugs for purposes of examination, test or analysis.	Firm has submitted copy of License Retention dated 09-05-2022 issued by FDA Mahrashtra State valid till 24-05-2027.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter:**

"DPI device: Monodose Inhaler RS01 Mod. 7 (Catalogue Code: "239700001AB")
Manufacturer: Berry Plastiape S.p.A"

1613.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	GMP status of the firm	GMP certificate issued based on the inspection dated 7th May 2019. Firm has submitted copy of GMP inspection report dated 20-10-2021 concluding that the firm is operating at good level of GMP compliance.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of Grant of additional section dated 27-10-2020 specifying Dry Powder Inhaler Capsule (General) - New section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17609: 16-06-2022
	Details of fee submitted	PKR 75,000/-: 25-05-2022
	The proposed proprietary name / brand name	**INDACTURA DPI Capsules 150mcg + 320mcg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Indacaterol (as Acetate)……150 mcg Mometasone Furoate…….320 mcg Each delivered dose contains: Indacaterol (as Acetate)……125 mcg Mometasone Furoate…….260 mcg
	Pharmaceutical form of applied drug	Rotacaps
	Pharmacotherapeutic Group of (API)	LABAs and Inhaled synthetic corticosteroid
	Reference to Finished product specifications	In house
	Proposed Pack size	10's, 30's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Atectura Breezhaler by Novartis Europharm Limited **EMA** Approved.
	For generic drugs (me-too status)	NA
	Name and address of API manufacturer.	**Indacaterol Acetate:** Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Dist - Thane- Zone 4, Maharashtra State, India. **Mometasone Furoate:** Aarti Industries Limited Plot No E-50, MIDC, Tarapur, Taluka & District-Palghar, 401506 Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Indacaterol acetate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months. **Mometasone Furoate:** Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against Atectura 150/160mcg DPI capsule (Batch No BUE50) of Novartis. Firm has also submitted results of invitro comparative delivered dose uniformity and aerodynamic particle size distribution for their product against the Atectura 150/160mcg DPI capsule of Novartis
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Indacaterol Acetate:** Melody Healthcare Pvt. Ltd. Plot No. J-73, M.I.D.C, Tarapur, Boisar, Dist. Palghar 401506, Dist - Thane- Zone 4, Maharashtra State, India. **Mometasone Furoate:** Aarti Industries Limited Plot No E-50, MIDC, Tarapur, Taluka & District-Palghar, 401506 Maharashtra State, India.
API Lot No.	**Indacaterol acetate:** ICA/08/21 **Mometasone Furoate:** MF-20016(JM-01)-001
Description of Pack (Container closure system)	Alu-alu blister

Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-C-1834-S	NPD-C-1835-S	NPD-C-1836-S
Batch Size	6000 capsule	6000 capsule	6000 capsule
Manufacturing Date	01-2022	01-2022	01-2020
Date of Initiation	18-02-2022	18-02-2022	18-02-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Empator 10mg Tablets" which was presented in 291st meeting of Registration Board wherein the Board decided to approve registration of this product Date of inspection: 6th August, 2019. According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Indacaterol acetate:** Firm has submitted copy of GMP certificate (No. 6100560) dated 09-07-2021 issued by FDA Mahrashtra. The certificate is valid till 08-07-2022. Firm has also submitted copy of Form 29 License to manufacture drugs for purposes of examination, test or analysis (Test Licence No: 201525228 dated 05-01-2021 valid till 04-01-2024. **Mometasone Furoate:** Firm has submitted copy of GMP certificate (No. 92338/2020/11/32133) dated 10-06-2020 issued by FDA Mahrashtra. The certificate is valid till 09-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Indacaterol acetate:** Firm has submitted copy of commercial invoice cleared dated 30-08-2021 specifying import of 40g Indacaterol acetate. The commercial invoice is attested by AD (I&E) DRAP field office. **Mometasone Furoate:** Firm has submitted copy of commercial invoice cleared dated 14-07-2021 specifying import of 0.040Kg Mometasone Furoate. The commercial invoice is attested by AD (I&E) DRAP field office.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

DPI device: Monodose Inhaler RS01 Mod. 7 (Catalogue Code: "239700001AB")
Manufacturer: Berry Plastiape S.p.A

Sr. No	Shortcomings communicated	Response by the firm
1.	API stability study data of Indacaterol acetate is till 12 months only.	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 18 months.
2.	Further justify how drug substance was procured from a manufacturer which holds Licence to manufacture drugs for purposes of examination, test or analysis.	Firm has submitted copy of License Retention dated 09-05-2022 issued by FDA Mahrashtra State valid till 24-05-2027.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter:**

"DPI device: Monodose Inhaler RS01 Mod. 7 (Catalogue Code: "239700001AB")
Manufacturer: Berry Plastiape S.p.A"

Case No. 03: M/s British pharmaceuticals, Lahore. (New / Additional Section)

Firm has submitted copy of letter of grant of additional section dated 11-02-2019 for following 3 sections.

- Tablet Section (General) (New)
- Capsule Section (General) (New)
- Dry Powder Suspension Section (General) (New)

Now the following applications have been marked as per the details mentioned in the table below:

Name of Section	No of molecules	No of products
Tablet Section (General) (New)	01	02

Tablet Section (General) (New): 01 Molecule / 02 Product

1614.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 12-01-2022 specifying Tablet (general) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22084: 03-08-2022
	Details of fee submitted	PKR 30,000/-: 27-07-2022
	The proposed proprietary name / brand name	**BRICIP 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……250mg
	Pharmaceutical form of applied drug	white oblong film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipro Tablet 250mg by Bayer HealthCare Pharmaceuticals Inc. USA (**USFDA** Approved)
	For generic drugs (me-too status)	Ciproxin Tablet 250mg of M/s Bayer Pakistan (Pvt) Limited (Reg # 010118)
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification

		of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against novidat tablet of Sami Firm has submitted results of CDP for their product against novidat tablet of Sami
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/055/2020		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B1	T-B2	T-B3
Batch Size	1666 Tablet	1666 Tablet	1666 Tablet
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	08-05-2021	08-05-2021	08-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note for 5Kg Ciprofloxacin hydrochloride dated 11-06-2020 from Pharmagen.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit GMP certificate / inspection report of the drug product manufacturer.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance.
- Submit API stability data till complete shelf life since the real time stability data is only for 12 months.
- Justify why the qualitative composition of your product is different from that of innovator's product.
- Provide description of pharmaceutical development as per the CTD guidance document which specifies that "A brief information on the pharmaceutical development shall be included. This information specifies the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed".
- Submit information in section 3.2.P.2.1.1 as per the CTD guidance document which specifies that "Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product."
- Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.
- Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients.
- Provide complete analytical method of your drug product instead on attaching copy of an old version of USP monograph.
- Provide verification studies of the analytical method of drug product as per ICH guidelines since all the tests performed are not according to ICH guidelines.
- Provide COA of working standard / reference standard actually used in the analysis of drug product in section 3.2.P.6.
- Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section.
- Provide information in section 3.2.P.8.2 as per the CTD guidance document.
- Justify why dissolution test is not performed in stability studies.
- USP monograph specifies that the retention time for ciprofloxacin is 6.4 - 10.8min, while in your submitted analytical record the retention time of ciprofloxacin is below 6.4 minutes.
- USP monograph specifies the use of Ciprofloxacin Ethylenediamine Analog in standard solution as system suitability solution and that The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0, respectively, while your analysis does not show any other peak within the relative retention time of 0.7 and 1.0.
- Submit evidencd of column oven having capacity to maintain column temperature at 30°.
- Submit Reference of previous approval of applications with stability study data of the firm (if any).
- Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.
- Provide proper raw data sheets showing calculation of results of assay instead of just submitting results without any calculation.
- Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

1615.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s British pharmaceuticals, 23-KM Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 12-01-2022 specifying Tablet (general) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22085: 03-08-2022
	Details of fee submitted	PKR 30,000/-: 27-07-2022
	The proposed proprietary name / brand name	**BRICIP 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin (as hydrochloride) ……500mg
	Pharmaceutical form of applied drug	white oblong film coated tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cipro Tablet 250mg by Bayer HealthCare Pharmaceuticals Inc. USA (**USFDA** Approved)
	For generic drugs (me-too status)	Ciproxin Tablet 250mg of M/s Bayer Pakistan (Pvt) Limited (Reg # 010118)
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6

		months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against novidat tablet of Sami Firm has submitted results of CDP for their product against novidat tablet of Sami
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00510011/055/2020		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B1	T-B2	T-B3
Batch Size	834 Tablet	834 Tablet	834 Tablet
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	08-05-2021	08-05-2021	08-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 02-09-2020. The GMP certificate was granted based on inspection dated 22-06-2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of delivery note for 5Kg Ciprofloxacin hydrochloride dated 11-06-2020 from Pharmagen.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted by the firm
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit GMP certificate / inspection report of the drug product manufacturer.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance.
- Submit API stability data till complete shelf life since the real time stability data is only for 12 months.
- Justify why the qualitative composition of your product is different from that of innovator's product.
- Provide description of pharmaceutical development as per the CTD guidance document which specifies that "A brief information on the pharmaceutical development shall be included. This information specifies the justification of formulation and method of manufacturing. It is also important that critical quality attributes (CQAs) and Critical Process Parameters (CPP) shall be discussed".
- Submit information in section 3.2.P.2.1.1 as per the CTD guidance document which specifies that "Discussion shall be provided for the key physicochemical characteristics (e.g. water content, solubility, particle size distribution, polymorphic or solid state form) of the Drug Substance(s) that can influence the performance of the Drug Product."
- Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.
- Clarify why you have mentioned not applicable for all section of 3.2.P.4 excipients, while your formulation contains excipients.
- Provide complete analytical method of your drug product instead on attaching copy of an old version of USP monograph.
- Provide verification studies of the analytical method of drug product as per ICH guidelines since all the tests performed are not according to ICH guidelines.
- Provide COA of working standard / reference standard actually used in the analysis of drug product in section 3.2.P.6.
- Provide information in section 3.2.P.8.1 as per the CTD guidance document since you have not submitted any information in this section.
- Provide information in section 3.2.P.8.2 as per the CTD guidance document.
- Justify why dissolution test is not performed in stability studies.
- USP monograph specifies that the retention time for ciprofloxacin is 6.4 - 10.8min, while in your submitted analytical record the retention time of ciprofloxacin is below 6.4 minutes.
- USP monograph specifies the use of Ciprofloxacin Ethylenediamine Analog in standard solution as system suitability solution and that The relative retention times for ciprofloxacin ethylenediamine analog and ciprofloxacin are 0.7 and 1.0, respectively, while your analysis does not show any other peak within the relative retention time of 0.7 and 1.0.
- Submit evidencd of column oven having capacity to maintain column temperature at 30°.
- Submit Reference of previous approval of applications with stability study data of the firm (if any).
- Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.
- Provide proper raw data sheets showing calculation of results of assay instead of just submitting results without any calculation.
- Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

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

Case No. 04: M/s Titlis Pharma (Pvt) Ltd. Lahore. (New / Additional Section)

Firm has submitted copy of letter of grant of additionall section under Drug Manufacturing License (DML No. 000779) dated 10-05-2022. The letter specifies following section:

1. Tablet Section-II (General)
2. Dry powder suspension (General)
3. Dry powder sachet section (General)

Now the following applications have been marked as per the details mentioned in the table below:

Name of Section	No of molecules	No of products
Dry powder suspension (General)	01	02

Tablet Section (General) (New): 01 Molecule / 02 Product

1616.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Titlis Pharma (Pvt) Ltd. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Ltd. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 05-11-2020 issued on the basis of inspection dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additionall section under Drug Manufacturing License (DML No. 000779) dated 10-05-2022. The letter specifies following section: 1. Tablet Section-II (General) 2. Dry powder suspension (General) 3. Dry powder sachet section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22073: 03-08-2022
	Details of fee submitted	PKR 30,000/- : 15-07-2022
	The proposed proprietary name / brand name	**CIPROLIS 125mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Ciprofloxacin HCl……125mg
	Pharmaceutical form of applied drug	Light pinkgranular powder with strawberry flavoured filled in 60ml amber color glass bottle
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	**Registration Board in its 269th meeting decided as under:** Keeping in view the following statement written in Qualitative and quantitative composition "2.5 mL suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age, Registration Board decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA.
	For generic drugs (me-too status)	Novidat suspension by Sami
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial triangle, Kahuta road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Novidat suspension of Sami Pharmaceuticals.

		Firm has submitted results of CDP for their product against the comparator product Novidat suspension of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial triangle, Kahuta road, Islamabad		
API Lot No.	CPX1279		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-03	CP-04	CP-05
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	27-11-2021	27-11-2021	27-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-02-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

- The label claim of the applied product is not in line with the reference product in terms of salt form as well as equivalency, revise the label claim along with submission of full fee of registration.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.

- Provide verification studies of drug substance from drug product manufacturer.
- Justify the assay testing of drug substance using UV method contrary to that recommended by the innovator's product.
- Submmit COA of relevant batch of API i.e. Lot No. CPX1279 from Vision pharmaceuticals in section 3.2.S.4.4.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance.
- Justify the stability study data of ciprofloxacin micro-pellets from Vision pharmaceuticals initiated in 2013 and completed in 2016 in which ciprofloxacin base is mentioned, while M/s Vision pharmaceuticals was manufacturing ciprofloxacin pellets using ciprofloxacin HCl before Registration Board took the decision to revise the salt form to ciprofloxacin base in its 290th meeting which was held on 3rd - 4th July, 2019. Justify how the salt form in stability study data of previous batches was changed.
- Justify the use of sugar and poly succar ultra DM as sweetner while you are already using taste masked granules in your formulation.
- Justify the use of xanthan gum as suspending agent along with granules in the formulation while the reference product contains no suspending agent.
- Justify how 71.429mg/1ml of ciprofloxacin granules is equivalent to 25mg ciprofloxacin base per ml.
- Justify the use of sodium benzoate anhydrous in your formulation while the pH is already controlled by the drug substance manufacturer at pellets stage and pH test is specified in COA of drug substance. Furthermore, the reference product contains oil based diluent for which pH is not required to be controlled.
- Justify the use of citric acid in your formulation as buffering agent which is not used by the reference product and the reference product contains oil based diluent for which pH is not required to be controlled.
- Justify the use of flavour in your formulation while you are already using taste masked granules.
- Justify the use of aerosil in your formulation.
- Provide details about the diluent which to be used with the applied product in section 3.2.P.1.
- Provide complete module 3.2.P for the diluent which will be used in the administration of applied product as per the decision of 290th and 313th meeting of Registration Board.
- Justify why the qualitative composition of applied product is different from that of innovator's product, and also provide compatibility studies.
- Justify why pharmaceutical equivalence studies are not conducted against the innovator's product.
- Provide microbiological attributes of the applied product in section 3.2.P.2.5 as per USP monograph.
- Submit preservative effectiveness studies in section 3.2.P.2.5.
- Submit compatibility studies of the applied product along with recommended diluent.
- Justify the pH test in your specification since no such test is recommended in USP monograph.
- Justify why Microbial Enumeration Tests is not mentioned in your specifications while it is recommended by USP.
- Justify the analytical method of assay and dissolution test in which initial reconstitution with water is mentioned while USP recommends to use the particular diluent for this purpose. Justify how your analytical method complies USP monograph.
- Justify why identification test using diode array detector is not performed and mentioned in analytical method.
- Justify why you are using different column in assay test as that recommended by USP.
- Submit evidence of diode array detector which is required for identification test as per USP monograph.
- Submit evidence of column oven which is required to maintain column temperature at 40° and 30° for assay and dissolution test.
- Submit evidence of autosampler with HPLC having capacity to maintain 10° which is required to perform assay and dissolution test as per USP monograph.
- Provide details of the exact concentrations of the solutions and its preparation method which are used to perform accuracy, and precision studies in analytical method verification studies.
- Justify how you are using ciprofloxacin HCl manufactured by Shangyu Jingxin pharmaceuticals for the testing of your product.
- The stability chromatograms for assay testing depicts that ciprofloxacin HCl is tested while the applied product contains ciprofloxacin base. Clarification is required in this regard.

- Justify the manufacturing of stability batches in November 2021 while your section was approved on 10-05-2022.
- Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.
- Clarification regarding reconstitution diluent used for the product development and stability studies.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).
    - Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
    - Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
    - Record of Digital data logger for temperature and humidity monitoring of both stability chambers.

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

1617.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Titlis Pharma (Pvt) Ltd. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Ltd. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 05-11-2020 issued on the basis of inspection dated 30-09-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of additionall section under Drug Manufacturing License (DML No. 000779) dated 10-05-2022. The letter specifies following section: 1. Tablet Section-II (General) 2. Dry powder suspension (General) 3. Dry powder sachet section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22072: 03-08-2022
	Details of fee submitted	PKR 30,000/- : 15-07-2022
	The proposed proprietary name / brand name	**CIPROLIS 250mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension contains: Ciprofloxacin HCl……250mg
	Pharmaceutical form of applied drug	Light pinkgranular powder with strawberry flavoured filled in 60ml amber color glass bottle
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Novidat suspension by Sami
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial triangle, Kahuta road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Novidat suspension of Sami Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Novidat suspension of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial triangle, Kahuta road, Islamabad
API Lot No.	CPX1279

Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-06	CP-07	CP-08
Batch Size	100 Bottles	100 Bottles	100 Bottles
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	27-11-2021	27-11-2021	27-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-02-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

- The label claim of the applied product is not in line with the reference product in terms of salt form as well as equivalency, revise the label claim along with submission of full fee of registration.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required." You have only submitted the specifications of API from the drug product manufacturer.
- Provide verification studies of drug substance from drug product manufacturer.
- Justify the assay testing of drug substance using UV method contrary to that recommended by the innovator's product.
- Submmit COA of relevant batch of API i.e. Lot No. CPX1279 from Vision pharmaceuticals in section 3.2.S.4.4.
- Submit COA of reference standard / working standard actually used in the analysis of drug substance.
- Justify the stability study data of ciprofloxacin micro-pellets from Vision pharmaceuticals initiated in 2013 and completed in 2016 in which ciprofloxacin base is mentioned, while M/s Vision pharmaceuticals was manufacturing ciprofloxacin pellets using ciprofloxacin HCl before Registration Board took the decision to revise the salt form to ciprofloxacin base in its 290th meeting which was held on 3rd - 4th July, 2019. Justify how the salt form in stability study data of previous batches was changed.

- Justify the use of sugar and poly succar ultra DM as sweetner while you are already using taste masked granules in your formulation.
- Justify the use of xanthan gum as suspending agent along with granules in the formulation while the reference product contains no suspending agent.
- Justify how 71.429mg/1ml of ciprofloxacin granules is equivalent to 25mg ciprofloxacin base per ml.
- Justify the use of sodium benzoate anhydrous in your formulation while the pH is already controlled by the drug substance manufacturer at pellets stage and pH test is specified in COA of drug substance. Furthermore, the reference product contains oil based diluent for which pH is not required to be controlled.
- Justify the use of citric acid in your formulation as buffering agent which is not used by the reference product and the reference product contains oil based diluent for which pH is not required to be controlled.
- Justify the use of flavour in your formulation while you are already using taste masked granules.
- Justify the use of aerosil in your formulation.
- Provide details about the diluent which to be used with the applied product in section 3.2.P.1.
- Provide complete module 3.2.P for the diluent which will be used in the administration of applied product as per the decision of 290th and 313th meeting of Registration Board.
- Justify why the qualitative composition of applied product is different from that of innovator's product, and also provide compatibility studies.
- Justify why pharmaceutical equivalence studies are not conducted against the innovator's product.
- Provide microbiological attributes of the applied product in section 3.2.P.2.5 as per USP monograph.
- Submit preservative effectiveness studies in section 3.2.P.2.5.
- Submit compatibility studies of the applied product along with recommended diluent.
- Justify the pH test in your specification since no such test is recommended in USP monograph.
- Justify why Microbial Enumeration Tests is not mentioned in your specifications while it is recommended by USP.
- Justify the analytical method of assay and dissolution test in which initial reconstitution with water is mentioned while USP recommends to use the particular diluent for this purpose. Justify how your analytical method complies USP monograph.
- Justify why identification test using diode array detector is not performed and mentioned in analytical method.
- Justify why you are using different column in assay test as that recommended by USP.
- Submit evidence of diode array detector which is required for identification test as per USP monograph.
- Submit evidence of column oven which is required to maintain column temperature at 40° and 30° for assay and dissolution test.
- Submit evidence of autosampler with HPLC having capacity to maintain 10° which is required to perform assay and dissolution test as per USP monograph.
- Provide details of the exact concentrations of the solutions and its preparation method which are used to perform accuracy, and precision studies in analytical method verification studies.
- Justify how you are using ciprofloxacin HCl manufactured by Shangyu Jingxin pharmaceuticals for the testing of your product.
- The stability chromatograms for assay testing depicts that ciprofloxacin HCl is tested while the applied product contains ciprofloxacin base. Clarification is required in this regard.
- Justify the manufacturing of stability batches in November 2021 while your section was approved on 10-05-2022.
- Provide stability study data in a proper sequence using separators to segregate the data of each time point and each batch along with relevant raw data sheets.
- Clarification regarding reconstitution diluent used for the product development and stability studies.
- Submit stability study data in section 3.2.P.8.3 as per the checklist approved by Registration Board in its 296th meeting and the CTD guidance document, which includes the following:
    - Reference of previous approval of applications with stability study data of the firm (if any)
    - Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
    - Documents for the procurement of API with approval from DRAP (in case of import).

○ Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. ○ Compliance Record of HPLC software 21CFR & audit trail reports on product testing. ○ Record of Digital data logger for temperature and humidity monitoring of both stability chambers.
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Case No. 03 Registration applications of CTD cases

a. New cases of local manufacturing

1618.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals (Pvt) Ltd Plot # 34, St No. NS-2, National Industrial Zone, Rawat, Islamabad.**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial triangle, Kahuta road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement between contract giver and acceptor dated 01-01-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-02-2019 based on the inspection dated 11-02-2019. The certificate specifies Dry Powder Injection (Steroids) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-02-2019 based on the inspection dated 11-02-2019. The certificate specifies Dry Powder Injection (Steroids) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24073: 01-09-2021
	Details of fee submitted	PKR 75,000/-: 22-06-2021
	The proposed proprietary name / brand name	**NAGSON 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 250 mg
	Pharmaceutical form of applied drug	Almost white to White powder filled in clear glass vial (USP Type-I) with rubber stopper and Flip off seal.
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cortizone injection by Global pharma

	Name and address of API manufacturer.	CRYSTAL PHARMA S.A Parque Tecnologico Parcela 105 4715, Boecillo (Valladolid), Spain
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Solucortef injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	CRYSTAL PHARMA S.A Parque Tecnologico Parcela 105 4715, Boecillo (Valladolid), Spain
API Lot No.	B0163/7CB16043
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	1116202	1216202	1216203
Batch Size	15000 vials	15000 vials	15000 vials
Manufacturing Date	11-2016	12-2016	12-2016
Date of Initiation	06-12-2016	21-12-2016	20-12-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. ES/064/17) issued by CIMA Spain based on inspection dated 09-01-2017. As per the GMP certificate it is valid for 3 years however this validity may be reduced or extended using regulatory risk management.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate issued by AD (I&E) DRAP dated 08-11-2016 specifying import of 100Kg hydrocortisone sodium succinate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide compatibility studies of the drug product along with recommended diluent.	As per USP monograph testing of sample is performed after reconstitution as reconstituted solution.
2.	Justify the drug product specifications submitted in section 3.2.P.5.1 which does not include the test of free hydrocortisone. Revise your specifications along with submission of requisite fee.	Test for free hydrocortisone is now added in the specs.
3.	Justify why the analytical method for assay test of drug product submitted in section 3.2.P.5.2 is entirely different from that specified in USP monograph, since USP recommends internal standard solution having 3mg/ml of Fluorometholone while your method does not specify the use of internal standard solution.	We are testing our product as per USP monograph and following HPLC method. **USP recommends internal standard solution having 3mg/ml of Fluorometholone while your method does not specify the use of internal standard solution.**
4.	Justify why the stability studies have been performed using UV method.	We are testing our products as per USP monograph by HPLC and by UV also as mentioned in BP. We have performed its all studies on HPLC.

		The analytical record submitted by the firm shows that the HPLC testing is not as per USP monograph in terms of injection volume, internal standard solution having Fluorometholone and the procedure to calculate results of assay based on addition of results of percentage of the labeled amount of hydrocortisone along with free hydrocortisone found in the test for Free Hydrocortisone

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will submit results of recently manufactured batches of the drug product in which testing has been performed as per USP monograph before issuance of Registration Letter.**
- **Firm will submit 7,500/- fee for revision of specifications by addition of test for free hydrocortisone as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1619.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals (Pvt) Ltd Plot # 34, St No. NS-2, National Industrial Zone, Rawat, Islamabad.**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial triangle, Kahuta road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement between contract giver and acceptor dated 01-01-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-02-2019 based on the inspection dated 11-02-2019. The certificate specifies Dry Powder Injection (Steroids) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals dated 25-02-2019 based on the inspection dated 11-02-2019. The certificate specifies Dry Powder Injection (Steroids) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24074: 01-09-2021
	Details of fee submitted	PKR 75,000/-: 22-06-2021
	The proposed proprietary name / brand name	**NAGSON 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone…… 500 mg
	Pharmaceutical form of applied drug	Almost white to White powder filled in clear glass vial (USP Type-I) with rubber stopper and Flip off seal.
	Pharmacotherapeutic Group of (API)	Corticosteroid, Glucocorticosteroid
	Reference to Finished product specifications	USP
	Proposed Pack size	1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Cortizone injection by Global pharma
	Name and address of API manufacturer.	CRYSTAL PHARMA S.A Parque Tecnologico Parcela 105 4715, Boecillo (Valladolid), Spain
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Hy-cortizone injection.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	CRYSTAL PHARMA S.A Parque Tecnologico Parcela 105 4715, Boecillo (Valladolid), Spain
API Lot No.	B0163/7CB16043
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	1116201	1216201	1216206
Batch Size	7204 vials	7204 vials	7204 vials
Manufacturing Date	11-2016	12-2016	12-2016
Date of Initiation	19-12-2016	05-12-2016	22-12-2016
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. ES/064/17) issued by CIMA Spain based on inspection dated 09-01-2017. As per the GMP certificate it is valid for 3 years however this validity may be reduced or extended using regulatory risk management.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate issued by AD (I&E) DRAP dated 08-11-2016 specifying import of 100Kg hydrocortisone sodium succinate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Provide compatibility studies of the drug product along with recommended diluent.	As per USP monograph testing of sample is performed after reconstitution as reconstituted solution.
2.	Justify the drug product specifications submitted in section 3.2.P.5.1 which does not include the test of free hydrocortisone. Revise your specifications along with submission of requisite fee.	Test for free hydrocortisone is now added in the specs.
3.	Justify why the analytical method for assay test of drug product submitted in section 3.2.P.5.2 is entirely different from that specified in USP monograph, since USP recommends internal standard solution having 3mg/ml of Fluorometholone while your method does not specify the use of internal standard solution.	We are testing our product as per USP monograph and following HPLC method. **USP recommends internal standard solution having 3mg/ml of Fluorometholone while your method does not specify the use of internal standard solution.**

4.	Justify why the stability studies have been performed using UV method.	We are testing our products as per USP monograph by HPLC and by UV also as mentioned in BP. We have performed its all studies on HPLC. **The analytical record submitted by the firm shows that the HPLC testing is not as per USP monograph in terms of injection volume, internal standard solution having Fluorometholone and the procedure to calculate results of assay based on addition of results of percentage of the labeled amount of hydrocortisone along with free hydrocortisone found in the test for Free Hydrocortisone**

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer will submit results of recently manufactured batches of the drug product in which testing has been performed as per USP monograph before issuance of Registration Letter.**
- **Firm will submit 7,500/- fee for revision of specifications by addition of test for free hydrocortisone as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

b. Deferred cases of local manufacturing

1620.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat Lahore.
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms is provided)
	GMP status of the firm	CCL Pharmaceuticals: GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance. Seraph Pharmaceuticals: GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Capsule Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 1782 dated 14-01-2021
	Details of fee submitted	Rs.50,000/- Dated 29-12-2020
	The proposed proprietary name / brand name	CEF-OD 200mg Capsule

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Cefixime (as trihydrate)……200mg
	Pharmaceutical form of applied drug	White to off-white powder filled in red/red hard gelatin capsule shells.
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixima Normon 200 Mg Hard Capsules EFG (Spain Approved)
	For generic drugs (me-too status)	Secure 200mg capsule of Wilshire
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cefim 200mg Capsule (Batch No. 135788, Mfg date 07-2019).

		Firm has submitted results of CDP for their product against Cefim 200mg Capsule (Batch No. 135788, Mfg date 07-2019). Firm has tested CDP in three dissolution medium and the results of f2 factor are within the acceptable limit.
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product. Firm has submitted report of verification studies of analytical method for the drug substance.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00244/015/2020		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	20-02-2020	20-02-2020	20-02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, Lahore dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of proforma invoice dated 07-01-2020 specifying purchase of 25Kg Cefixime (compacted).

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated in January / Feb 2020, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	Response by the firm
As per the drug substance specifications of the drug substance manufacturer i.e. Pharmagen Limited, the material complies BP specification and the analytical method also involves testing as per BP monograph. The drug product manufacturer i.e. Seraph Pharmaceutical has submitted drug substance specification as per USP and its analytical method is also as per USP monograph. Clarification is required in this regard how drug product manufacturer can use USP specifications including testing method while the drug substance complies BP monograph.	Firm has submitted revised specifications and analytical procedures of the drug substance as per BP monograph.
The verification studies of the analytical method of drug substance specifies a different column specifications as well as mobile phase. Further the procedure for assay specifies cefixime dry suspension and contains a different method for assay. Clarification is required in this regard.	Firm has submitted that verification studies have been performed according to BP specs and the report is attached which does not contains any date.
As per the analytical method submitted by the firm i.e. Seraph Pharmaceuticals, the flow rate is adjusted so that the retention time of cefixime is about 10 minutes, but as per the verification study report and system suitability testing, the retention time of 6 samples was not more than 3.5 minutes. Justify how the verification studies were concluded to be acceptable since the retention time is different from that specified in the method as well as USP monograph.	Firm has submitted that cefixime raw material was analysed as per BP monograph and BP defined method was also verified. In BP retention time is not specified for cefixime. However in product analysis JP method was followed with little deviation in flow rate so as to manage the samples.
The accuracy and recovery study in verification studies of the drug substance is performed by analysing samples having 80%, 100% and 120% of "A" or reference solution preparation. As per the method, the standard solution has a concentration of 0.2mg/ml while as per the accuracy and recovery table the amount of drug added is 20mg, 25mg and 30mg. Justification / clarification is required how 20, 25 and 30mg is equivalent to 80%, 100% and 120% of "A"	Firm has submitted that verification studies have been performed according to BP specs and the report is attached which does not contains any date.
The repeatability studies have been performed using sample concentration 0.012mg/ml, while neither standard solution or the sample solution has this concentration. Justification is required regarding this concentration to perform repeatability and intermediate precision in verification studies	Firm has submitted that verification studies have been performed according to BP specs and the report is attached which does not contains any date.
The COA of drug substance (Batch No. 00244/051/2020) from Pharmagen Limited specifies that the	Firm has submitted that COA from Pharmagen specifying the manufacturing date to be Feb 2020 and

manufacturing date is February 2020 and the COA has been signed on 19-02-2020, while as per the analytical report of the same batch from Seraph Pharmaceutical, the analysis is performed on 28-01-2020. Justification is required is this regard.	sign date 19-02-2020 is that of Batch number 00244/051/2020 while the report from Seraph pharma is not of the same batch instead is of Batch No 00244/015/2020. The same batch is also used for the formulation development and stability studies.
The COA of drug substance issued from the drug substance manufacturer specifies that the material complies BP specs while the drug product manufacturer concludes that the material complies USP specs. Clarification is required in this regard.	Firm has submitted that the material was tested as per BP specs and complied the specification s as defined in BP. Mistakenly the report was misinterpreted.
Provide justification of the selection of excipients, since the excipients used in the formulation are different from that of the FDA approved innovator product.	Firm has submitted that we have followed the innovator product approved by EMA named Cefixima 200mg Capsules by M/s Laboratories Normon. The excipient we selected are approximately same as that of the innovator product.
The average weight of the product mentioned in pharmaceutical equivalence studies is 335mg while the total weight of master formulation available in section 3.2.P.1 is 260mg. Justification is required in this regard.	In master formulation the weight of shell is not included. Without shell the weight is 260mg and if shell weight "75mg" is added, it makes 335mg weight per capsule.
Justify why the pharmaceutical equivalence as well as comparative dissolution profile was studied against comparator product instead of using innovator / reference product.	Due to unavailability of cefixime 200mg capsule by M/s Laboratoies Normon we have performed equivalence and CDP with comparator product. Moreover the comparator product is approved by DRAP, so we used that for comparative studies.
Provide details including batch number, manufacturing and expiry date of the comparator product used in product development studies.	Product name: Cefim 200mg capsule Batch No 135788 Mfg date: 07/2019 Exp date: 07/2021
Justify the dissolution specifications of NLT 80% in 90 minutes, since the JP monograph specifies this limit only for 100mg potency capsule.	Previously we applied for the registration of cefixime 400mg Capsule with innovator's specs as cefixime 400mg capsule is not defined by JP, USP or BP etc. The DRAP granted the registration with JP specs, in case of cefixime 200mg capsule although not defined by JP, we followed JP specs NLT 80%(Q) in 90 minutes keeping in view the case of cefixime 400mg capsule.
The USFDA review of innovator product of cefixime 400mg capsule reveals that the acceptance criteria for dissolution test should be NLT (Q) in 45 minutes using 7.2 pH phosphate buffer. Justify the results of comparative dissolution profile at 6.8 pH phosphate buffer in which the drug release of both test as well as comparator product was less than 70% in 45 minutes.	The USFDA specification defined are that of cefixime 400mg capsule while for cefixime 200mg, the USFDA recommends tablet dosage form not the capsule, so USFDA 400mg limits can only be used as reference but not mandatory for 200mg capsule. While JP limits are applied because of the point explained in aforementioned query justification.
Justify how exactly same results are obtained in verification studies of drug substance and the drug product.	The results of verification studies of druh product are different from drug substance while compiling dossier we mistakenly misplaced drug substance verification with drug product. Drug product verification studies are now attached.
The formulation development section specifies that the cefixime capsule uses red/red hard gelatin capsule shells, while the batch analysis in section 3.2.P.5.4 specifies that blue/blue hard gelatin capsule shells are used in the product. Clarification is required in this regard.	There was a typo mistake in the batch analysis section 3.2.P.5.4, where capsule color blue/blue is mentioned while we use capsule shel with red/red color.
As per the analytical report of finished product submitted in batch analysis in section 3.2.P.5.4 the results of water, dissolution and assay of Batch T001 are 4.12%, 96.23% and 101.12%, while the results of the same batch mentioned in initial time point of stability studies is 9.06%, 96.69% and 101.06% respectively for the above-mentioned tests. Clarification is required in this regard.	There was a typo mistake in the batch analysis report of T001. Correct report is attached.
Justify how the HPLC analysis was conducted for cefixime capsule in which retention time is around 3.3 minutes, while the JP monograph specifies that the retention time should be around 10 minutes.	JP method was followed for the analysis of cefixime capsule, however, to manage the samples a little deviation in the flow rate was commenced. But in routine analysis JP method was followed without any deviation.

Justify the HPLC analysis using ambient column temperature as mentioned on each chromatogram, since the JP monograph specifies that the column should be maintained at a constant temperature of 40°C.	Column temperature was maintained at 40°C but the column oven is operated manually independent of software so the software does not show the temperature. Now the column oven is replaced with a new oven which is operated with software, so new chromatograms will display the set temperature.
Justify the calculation of results of assay as well dissolution using a different formula as specified in JP monograph.	Firm has submitted new formula for calculation of assay and dissolution results along with revised method and raw data sheets.
Submit copy of commercial invoice as evidence of purchase of drug substance, since proforma invoice dated 07-01-2020 is submitted which does not confirm that the drug substance has been procured.	Firm has submitted copy of invoice (No. 1712), dated 24-01-2021 specifying cefixime compacted 25 Kg Batch number 00244-01/015/2020.
The stability studies specifies that cefixime (compacted) having batch number 00244/015/2020 was used for product development and stability studies. As per the COA of that particular batch, the batch was manufactured in January 2020 and the batch was released after testing on 23-01-2020. Justify how the proforma could be generated on 07-01-2020 even before the analysis and release of the batch.	Proforma invoice is a general agreement (quotation) invoice that is signed between two parties (seller and buyer). It is not for a particular batch. For a particular batch commercial invoice is authentic evidence of purchase.
As per the COA provided in section 3.2.S.4.4. the batch number of drug substance used is 00244/051/2020, while as per stability data the batch number of drug substance used in stability studies is 00244/051/2020. Clarification is required in this regard.	The batch 00244/015/2020 was used for stability studies. A typographic mistake occurred. The COA of the particular batch is also provided.
Provide batch manufacturing record (BMR) of three stability batches.	Firm has submitted copy of BMR of the three stability batches
Provide record of data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger of temperature and humidity monitoring.

Decision of 307th meeting of Registration Board:

Deferred for following:

- Scientific justification for having retention time around 3.3 minutes in assay testing while JP monograph specifies that retention time should be 10 minutes.
- Scientific justification for adaptation of dissolution acceptance criteria NLT 80% in 90 minutes, since JP monograph specifies this limit only for 100mg potency capsule while USFDA review of innovator product of cefixime 400mg capsule reveals that the acceptance criteria for dissolution test should be NLT (Q) in 45 minutes using 7.2 pH phosphate buffer.

Response by the firm:

Reason for deferment	Response by the firm
Scientific justification for having retention time around 3.3 minutes in assay testing while JP monograph specifies that retention time should be 10 minutes.	• The JP pharmacopoeia does not specify flow rate in the chromatographic conditions for the assay testing. Since flow rate was not specified in JP monograph therefore the flow rate was adjusted during verification studies and system suitability studies. The flow rate at which all the verification parameters and system suitability requirements were met, was finally selected for the assay testing. The retention time of around 4 to 5 minutes was achieved with the flow rate. • The same chromatographic conditions were applied for reference as well as sample solution and both produced similar retention time. The relative retention time for the sample peak was found to be within limit of 0.8 to 1.2. • Furthermore, the USP general chapter (621) CHROMATOGRAPHY under the heading of system suitability specifies that the flow rate for an HPLC method can be adjusted by ±50%. Keeping in view the above scientific justifications we have selected the flow rate which achieved the retention time of 4 to 5 minutes. Therefore, we request that our data may be accepted based upon our scientific justification and supportive data.

Scientific justification for adaptation of dissolution acceptance criteria NLT 80% in 90 minutes, since JP monograph specifies this limit only for 100mg potency capsule while USFDA review of innovator product of cefixime 400mg capsule reveals that the acceptance criteria for dissolution test should be NLT (Q) in 45 minutes using 7.2 pH phosphate buffer.	There are various differences in dissolution test parameters in JP monograph and the FDA innovator product as well as USP. The differences are as follows: **Parameter** / **JP** / **FDA** RPM / 50 / 100 Apparatus / Paddle (II) / Basket (I) Medium / Disodium hydrogen phosphate-citric acid buffer solution / 6.8g/L of monobasic potassium phosphate in water, adjusted with 1N sodium hydroxide pH of the Medium / 7.5 / 7.2 The FDA/ USP method specifies different acceptance criteria i.e. NL T (Q) in 45 minutes as compared to JP monograph. Since FDA method has 2 times higher RPM, a different dissolution apparatus and dissolution medium, and the pH of both medium is also different. Based on these differences in RPM and pH it is evident that performing dissolution test using FDA/ USP conditions will achieve earlier dissolution. To further verify we have also performed dissolution testing of the same batch using FDA/ USP conditions and our results were also more than 80% in 45 minutes. Firm has also submitted results of dissolution test as per FDA method on all of the three batches. The results of all batches were above 90% in 45 minutes.

Discussion of 312nd meeting of Registration Board:
Registration Board deliberated that the product monograph is present in Japanese pharmacopoeia however the dissolution test in JP specifies only 50mg and 100mg strength while the applied product is cefixime 200mg capsule. Therefore, the Board deferred the case for further deliberation in forthcoming meeting.

Proceedings of 313rd meeting of Registration Board:
Registration Board deliberated the matter in detail and after thoroughly reviewing the product review documents of innovator product Suprax 400mg capsule and the monograph of cefixime capsule in Japanese Pharmacopeia 17th Edition, decided to approve the following monograph for cefixime capsule. The Board further decided that the monograph shall be notified for information of all manufacturers and regulatory laboratories. The Board further advised the manufacturer's / importers having registration of the said product to revise their specifications in the light of approved monograph within 6 months after its notification.

Decision of 316th meeting of Registration Board:
Deferred for submission of stability study data of three commercial batches manufactured by the contract manufacturer in section 3.2.P.8.3 as per the 6-points checklist provided in Form 5-F guidance document (PE&R/GL/AF/004) approved by the Registration Board.

Submission by the firm:
Firm has submitted that Registration Board in its 321st meeting decided to also accept product development data / stability data of trial batches manufactured by contract manufacturer. The same stability study data of the contract manufacturer of same batches is already approved by the Board in its 316th meeting of Registration Board.

Decision: Approved with Manufacturer's specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

- **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1621.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.

	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16132: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 19-05-2021 + PKR 25,000/-: 26-05-2021
	The proposed proprietary name / brand name	**GENFIXIM 100mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……100mg
	Pharmaceutical form of applied drug	White to light yellow powder filled in amber colored glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cebosh dry suspension of Bosch pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00243/342/2017		
Description of Pack (Container closure system)	Amber color glass bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180012	180013	180015
Batch Size	5,000 bottles	5,000 bottles	5,000 bottles
Manufacturing Date	02-2018	02-2018	04-2018
Date of Initiation	22-03-2018	19-03-2018	19-04-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous PSI has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 09-02-2018 specifying purchase of 25Kg Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, HPLC chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted drug substance specifications from API manufacturer as well as Cunningham pharmaceuticals dated February 2021. **The specifications of Cunningham pharma are different from API manufacturer as well as BP monograph. Further the API specs are of February 2021 while stability testing was initiated in March 2018.**
2.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board and in line with ICH guidelines specifying the exact concentration of each solution and the detailed procedure for each test.	Firm has submitted verification studies of analytical method of drug substance. The analytical method mentioned in verification studies is different from the analytical procedure submitted in section 3.2.S.4.2. Furthermore the method specifies HPLC technique while the calculation method specifies UV absorbance values.
3.	Submit COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted COA of working standard from Pharmagen Limited.
4.	Submit stability study data of the drug substance (cefixime trihydrate in micronized form) from the drug substance manufacturer as per zone IV-A conditions.	Firm has again submitted the same stability data without clarification whether the cefixime was compacted or micronized.
5.	Provide complete master formulation for each bottle in section 3.2.P.1.	Firm has submitted master formulation per bottle.
6.	Provide details of reconstitution solvent / diluent along with its exact volume which is to be used for reconstitution of the drug product.	Water for injection 20ml is the diluent for reconstitution.
7.	Justify why the pharmaceutical equivalence studies are not performed against the innovator / reference product.	No response submitted by the firm, firm has again submitted the same pharmaceutical equivalence report. **Firm has not performed preservative effectiveness studies.**
8.	Justify why comparative dissolution profile / drug release studies are not performed for your product	Firm has submitted that test for CDP is not mentioned in USP monograph.

	since USFDA has recommended such studies for cefixime suspension.	
9.	Submit data of compatibility of the drug product along with reconstitution solvent in section 3.2.P.2.6.	Firm has submitted results of compatibility studies.
10.	Justify why the test for deliverable volume is not added in drug product specification as recommended in USP monograph. Revise your product specifications in line with USP monograph along with submission of fee for revision of specifications.	Firm has submitted revised specifications in which test of deliverable volume is also added. Firm has not submitted any fee for change of specifications.
11.	Provide details about the standard solution preparation instead of just using the general statement "0.2mg/ml of USP cefixime RS in solution C" as mentioned in USP monograph.	Firm has submitted revised specifications in which detailed method of standard solution preparation is mentioned.
12.	Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.	Firm has submitted revised specifications in which detailed method of sample solution preparation is mentioned.
13.	Justify the alternate method for assay testing of the drug product which is based on UV analysis.	Firm has submitted that UV method is only for final mix stage in order to save time during the process.
14.	The concentration of standard solution is 0.2mg/ml while your linearity studies are conducted between 0.008mg/ml to 0.02mg/ml in which does not include the concentration of standard solution. Justify your results.	Method verification of finished product has been revised as per ICH guidelines. **Firm has not justified previous verification studies.**
15.	The repeatability, reproducibility and accuracy studies are reported without specifying the exact concentration of each solution which is tested. Provide results of your verification studies in the light of ICH guidelines.	Method verification of finished product has been revised as per ICH guidelines. **Firm has not justified previous verification studies.**
16.	Justify how same verification studies are used for the analytical method of cefixime capsule, and suspension as well.	Method verification of finished product has been revised as per ICH guidelines. **Firm has not justified previous verification studies.**
17.	For Batch No. 180012, the results of batch analysis (performed on 19-02-2018) was 109.86% while the results in initial stability studies at accelerated (performed on 22-03-2018) was 102.65% while the results in initial stability studies at real time (performed on 22-03-2018) was 104.71%. Justify how such significant difference in assay value exists and further justify how the results of initial stability is different for accelerated and real time studies.	It was a typographical error.
18.	For Batch No. 180013, the results of batch analysis (performed on 22-02-2018) was 104.71% while the results in initial stability studies at accelerated (performed on 19-03-2018) was 101.23% while the results in initial stability studies at real time (performed on 19-03-2018) was 104.62%. Justify how such significant difference in assay value exists and further justify how the results of initial stability is different for accelerated and real time studies.	It was a typographical error.
19.	Specify the date of initiation of stability studies for the batch number 180015.	19-04-2018

Decision of 320th meeting of Registration Board:

Deferred for following:

- Scientific justification for having different specifications of the drug substance from that of API manufacturer as well as BP monograph.

- Scientific justification how a revised method of February 2021 can represent the results of the stability studies which were initiated in March 2018.
- Scientific justification for performing verification studies of the analytical method of drug substance using a different analytical method from that specified in section 3.2.S.4.2.
- Submission of stability study data of three batches of cefixime trihydrate (micronized) from the API manufacturer as per zone IV-A conditions.
- Submission of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product.
- Submission of preservative effectiveness studies.
- Submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Scientific justification how the results of at zero month time point can be different for accelerated and real time conditions.

Response by the firm:

Sr. No	Reasons for deferment	Response by the firm
1.	Scientific justification for having different specifications of the drug substance from that of API manufacturer as well as BP monograph	The firm has submitted revised specifications for drug substance as per B.P.
2.	Scientific justification how a revised method of February 2021 can represent the results of the stability studies which were initiated in March 2018.	The format of SOP For Cefixime was revised in February 2021. However, the testing method was same as that of stability studies initiated in 2018. We didn't change the testing method of API, only format was revised with new revision number and date.
3.	Scientific justification for performing verification studies of the analytical method of drug substance using a different analytical method from that specified in section 3.2.S.4.2.	The firm has stated that the verification studies were performed for analytical method as provided in the section 3.2.S.4.2. Furthermore, the calculation method is also as per B.P. The firm has submitted relevant chromatogram and raw data sheets.
4.	Submission of stability study data of three batches of cefixime trihydrate (micronized) from the API manufacturer as per zone IV-A conditions.	The firm has submitted stability study data of three batches (real time: 36 months: Accelerated: 06 months) according to the conditions of Zone IV-A. Batches: 00243/001/2018, 00243/100/2018, 00243/200/2018
5.	Submission of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product.	Pharmaceutical equivalence and CDP studies have been performed against Cefspan dry suspension mfg by M/s Barret Hodgson. The firm has submitted the relevant data including calculations of F2 values.
6.	Submission of preservative effectiveness studies.	The firm has performed preservative effectiveness studies and presented the data in relevant section (document no. SOP-MB/02-0238).
7.	Submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	The firm has submitted Rs. 7,500/- for revision of specifications vide challan number 947937869.
8.	Scientific justification how the results of at zero-month time point can be different for accelerated and real time conditions.	The results in raw data sheets are same for accelerated and real time stability at initial time point whereas in stability summary sheets the results are different, it was a typographical error. We are submitting revised stability summary sheets.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

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

1622.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 29-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Dry powder suspension (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying Dry powder suspension (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 16133: 10-06-2021
	Details of fee submitted	PKR 50,000/-: 19-05-2021 + PKR 25,000/-: 26-05-2021
	The proposed proprietary name / brand name	**GENFIXIM 200mg/5ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml of reconstituted suspension Contains: Cefixime as trihydrate……200mg
	Pharmaceutical form of applied drug	White to light yellow powder filled in amber colored glass bottle
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	30 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime suspension **(USFDA** Approved)
	For generic drugs (me-too status)	Cefim suspension by Hilton

	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cebosh dry suspension of Bosch pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
API Lot No.	00243/342/2017
Description of Pack (Container closure system)	Amber color glass bottle
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180011	180016	180048
Batch Size	5,000 bottles	5,000 bottles	5,000 bottles
Manufacturing Date	02-2018	04-2018	08-2018
Date of Initiation	19-03-2018	22-03-2018	22-03-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous PSI has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP, dated 11-01-2019. The GMP certificate was granted based on inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 09-02-2018 specifying purchase of 25Kg Cefixime (micronized).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, HPLC chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings Communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Firm has submitted drug substance specifications from API manufacturer as well as Cunningham pharmaceuticals dated February 2021. **The specifications of Cunningham pharma are different from API manufacturer as well as BP monograph. Further the API specs are of February 2021 while stability testing was initiated in March 2018.**
2.	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board and in line with ICH guidelines specifying the exact concentration of each solution and the detailed procedure for each test.	Firm has submitted verification studies of analytical method of drug substance. The analytical method mentioned in verification studies is different from the analytical procedure submitted in section 3.2.S.4.2. Furthermore the method specifies HPLC technique while the calculation method specifies UV absorbance values.
3.	Submit COA of reference standard actually used in the analysis of drug substance and drug product.	Firm has submitted COA of working standard from Pharmagen Limited.
4.	Submit stability study data of the drug substance (cefixime trihydrate in micronized form) from the	Firm has again submitted the same stability data without clarification whether the cefixime was compacted or micronized.

	drug substance manufacturer as per zone IV-A conditions.	
5.	Provide complete master formulation for each bottle in section 3.2.P.1.	Firm has submitted master formulation per bottle.
6.	Provide details of reconstitution solvent / diluent along with its exact volume which is to be used for reconstitution of the drug product.	Water for injection 20ml is the diluent for reconstitution.
7.	Justify why the pharmaceutical equivalence studies are not performed against the innovator / reference product.	As innovator product is not available in Pakistan therefore we performed testing against Cebosh suspension. **Firm has not performed preservative effectiveness studies.**
8.	Justify why comparative dissolution profile / drug release studies are not performed for your product since USFDA has recommended such studies for cefixime suspension.	Firm has submitted that test for CDP is not mentioned in USP monograph.
9.	Submit data of compatibility of the drug product along with reconstitution solvent in section 3.2.P.2.6.	Firm has submitted results of compatibility studies.
10.	Justify why the test for deliverable volume is not added in drug product specification as recommended in USP monograph. Revise your product specifications in line with USP monograph along with submission of fee for revision of specifications.	Firm has submitted revised specifications in which test of deliverable volume is also added. Firm has not submitted any fee for change of specifications.
11.	Provide details about the standard solution preparation instead of just using the general statement "0.2mg/ml of USP cefixime RS in solution C" as mentioned in USP monograph.	Firm has submitted revised specifications in which detailed method of standard solution preparation is mentioned.
12.	Submit exact details of the assay preparation since the words "*Reconstitute sample as directed n the labelling"* should not be used in the method adopted by a firm. Instead provide details about the exact diluent along with volume in which reconstitution is to be carried out.	Firm has submitted revised specifications in which detailed method of sample solution preparation is mentioned.
13.	Justify the alternate method for assay testing of the drug product which is based on UV analysis.	Firm has submitted that UV method is only for final mix stage in order to save time during the process.
14.	The concentration of standard solution is 0.2mg/ml while your linearity studies are conducted between 0.008mg/ml to 0.02mg/ml in which does not include the concentration of standard solution. Justify your results.	Method verification of finished product has been revised as per ICH guidelines. **Firm has not justified previous verification studies.**
15.	The repeatability, reproducibility and accuracy studies are reported without specifying the exact concentration of each solution which is tested. Provide results of your verification studies in the light of ICH guidelines.	Method verification of finished product has been revised as per ICH guidelines. **Firm has not justified previous verification studies.**
16.	Justify how same verification studies are used for the analytical method of cefixime capsule, and suspension as well.	Method verification of finished product has been revised as per ICH guidelines. **Firm has not justified previous verification studies.**
17.	Justify how the results of initial stability is different for accelerated and real time studies.	Results of initial stability study are not different from accelerated and real time time studies. However, it was a typographical error. Results of Batch 180016 and Batch 180048 after correction are attached.
18.	Justify why the results of real time stability studies for batch 180016 and 180048 are exactly same.	It was a typographical error. Results of Batch 180016 and Batch 180048 after correction are attached.

Decision of 320th meeting of Registration Board:

Deferred for following:

- Scientific justification for having different specifications of the drug substance from that of API manufacturer as well as BP monograph.

- Scientific justification how a revised method of February 2021 can represent the results of the stability studies which were initiated in March 2018.
- Scientific justification for performing verification studies of the analytical method of drug substance using a different analytical method from that specified in section 3.2.S.4.2.
- Submission of stability study data of three batches of cefixime trihydrate (micronized) from the API manufacturer as per zone IV-A conditions.
- Submission of pharmaceutical equivalence and Comparative dissolution profile (CDP) against the innovator's product.
- Submission of preservative effectiveness studies.
- Submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Scientific justification how the results of initial stability can be different for accelerated and real time conditions.

Submission by the firm:

Sr. No	Reasons for deferment	Response by the firm
1.	Scientific justification for having different specifications of the drug substance from that of API manufacturer as well as BP monograph	The firm has submitted revised specifications for drug substance as per B.P.
2.	Scientific justification how a revised method of February 2021 can represent the results of the stability studies which were initiated in March 2018.	The format of SOP For Cefixime was revised in February 2021. However, the testing method was same as that of stability studies initiated in 2018. We didn't change the testing method of API, only format was revised with new revision number and date.
3.	Scientific justification for performing verification studies of the analytical method of drug substance using a different analytical method from that specified in section 3.2.S.4.2.	The firm has stated that the verification studies were performed for analytical method as provided in the section 3.2.S.4.2. Furthermore, the calculation method is also as per B.P. The firm has submitted relevant chromatogram and raw data sheets.
4.	Submission of stability study data of three batches of cefixime trihydrate (micronized) from the API manufacturer as per zone IV-A conditions.	The firm has submitted stability study data of three batches (real time: 36 months : Accelerated : 06 months) according to the conditions of Zone IV-A. Batches: 00243/001/2018, 00243/100/2018, 00243/200/2018
5.	Submission of pharmaceutical equivalence and Comparative Dissolution Profile (CDP) against the innovator's product.	Pharmaceutical equivalence and CDP studies have been performed against Cefspan dry suspension mfg by M/s Barret Hodgson. The firm has submitted the relevant data including calculations of F2 values.
6.	Submission of preservative effectiveness studies.	The firm has performed preservative effectiveness studies and presented the data in relevant section (document no. SOP-MB/02-0238).
7.	Submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	The firm has not submitted any fee.
8.	Scientific justification how the results of at zero-month time point can be different for accelerated and real time conditions.	The results in raw data sheets are same for accelerated and real time stability at initial time point whereas in stability summary sheets the results are different, it was a typographical error. We are submitting revised stability summary sheets.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved. Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

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

1623.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories (Pvt) Ltd. 9.5Km Sheikhupura Road Lahore.**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals (Pvt) Ltd. Plot No. 81, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 01-04-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 19-04-2019 based on the inspection dated 01-04-2019. The GMP certificate specifies Capsule (cephalosporin) section.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML of M/s Cunningham Pharmaceuticals (Pvt) Ltd dated 13-06-2016 specifying capsule (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 14887: 31-05-2021
	Details of fee submitted	PKR 50,000/-: 28-04-2021 + PKR 25,000/-: 28-05-2021
	The proposed proprietary name / brand name	**PDFIM 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime as trihydrate……400mg
	Pharmaceutical form of applied drug	Hard gelatin capsule size # 0 with blue colored body and cap having white to yellow colored powder
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	1x5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties,

		solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Cebosh capsule.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00244-11/322/2017 00244-11/344/2017 00244-07/146/2018		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	180010	180042	180059
Batch Size	100,000 capsule	10,000 capsule	10,000 capsule

Manufacturing Date	02-2018	07-2018	09-2018
Date of Initiation	17-03-2018	07-08-2018	16-10-2018
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP dated 11-01-2019 based on the inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 09-01-2018 specifying purchase of 7Kg Cefixime (compacted) Lot No. 00244-11/322/2017 and 43 Kg cefixime (compacted) Lot No. 00244-11/344/2017. Firm has submitted copy of commercial invoice dated 31-08-2018 specifying purchase of 50Kg Cefixime (compacted) Lot No. 00244-07/146/2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted report of stability batches however it is not depicting the audit trail for the analysis of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcomings communicated	**Response by the firm**
Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Copies of method of analysis from drug substance & drug product manufacturer is submitted by the firm.
As per BP method the reference standard solution concentration is 0.01mg/ml while as per the linearity results in verification report of analytical method of drug substance the analysis was made from 0.5mg/ml to 1.4mg/ml. Justify how your linearity studies corresponds to the analytical method of BP.	We performed our linearity studies according to reference solution (a) i.e. 1.0mg/ml and used 0.5mg/ml to 1.4mg/ml concentrations for the linearity study.
You have claimed JP specifications for the drug product and have used drug substance complying BP specifications. Justification is required in this regard.	Firm has not submitted any justification
Submit data in section 3.2.S.4.4 as per the guidance document approved by Registration Board which specifies that "Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture, since the submitted COA of three batches of API are of different batches than that used in the manufacturing of stability batches.	Submitted COA of relevant batches of drug substance were used for production of commercial batches similar to that used in manufacturing of stability batches. Firm has not provided any COA of relevant batch of API as per the requirements of Form 5F
Justify why pharmaceutical equivalence has been peformed with Cebosh capsule instead of performing	Firm has not submitted any justification

pharmaceutical equivalence against the innovator / reference product.	
Justify how the formulation development has been completed without performing comparative dissolution profile (CDP) studies of your product against the innovator / reference product in three dissolution medium as recommended by WHO guidelines.	Comparative dissolution profile (CDP) was not the requirement at the time of product development. But now CDP has been performed with competitor product. No CDP is submitted by the firm.
Justify the alternate method for assay and dissolution testing of the drug product which is based on UV analysis, since no such alternate method is available in JP monograph.	Firm has not submitted any justification
Justify the dissolution specifications of NLT 80% in 90 minutes, since the JP monograph specifies this limit only for 100mg potency capsule.	Firm has submitted official monograph of JP. Firm has not submitted any justification
The USFDA review of innovator product of cefixime 400mg capsule reveals that the acceptance criteria for dissolution test should be NLT (Q) in 45 minutes using 7.2pH phosphate buffer. Justify how your product may considered equivalent to the innovator product.	Firm has not submitted any justification

- Firm has now submitted stability data sheets for 3 batches. Wherein significant different in assay values exist in accelerated study for batch 180010 (i.e. from 104.32% to 99.18% from initial time to 6 months).
- Similarly the results of initial time point for both accelerated and real time stability is different for both real time and accelerated stability.

Decision of 316th meeting of Registration Board:

Deferred for following:

- Submission of stability study data of three commercial batches of the drug product in which product testing has been conducted as per the product specification approved by Registration Board in its 313rd meeting and notified vide No.F.14-1/2022-PEC dated 14th March 2022.
- Firm shall submit the fee of Rs. 30,000 for revision in stability data, as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

Response by the firm:

Firm has submitted stability study data of 3 newly manufactured batches in which product testing has been performed as per the monograph for cefixime capsule approved by Registration Board for 6 months. The details of the newly manufactured batches is as under:

Manufacturer of API	Pharmagen Limited. Kot Nabi Bukshwala, 34 Km, Ferozepur Road, Lahore.		
API Lot No.	00244-10/193/2021		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	220026
Batch Size	2000 Capsule	2000 Capsule	50,000 capsule
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	15-03-2022	15-03-2022	28-03-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Additional Director DRAP dated 11-01-2019 based on the inspection dated 08-01-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 03-12-2021 specifying purchase of 7Kg Cefixime (compacted)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

- Capacity assessment of M/s Cunningham Pharmaceuticals Lahore was carried out on 12-11-2020 and the report was presented in 297th meeting of Registration Board. As per the report, firm has 3 HPLC systems and the reported available capacity in major areas is as under:

Sr. No	Section	Average Available capacity
1.	HPLC	75.52%
2.	Sterility testing	84.86 %

Decision: Approved with Manufacturer's specifications as approved by Registration Board in its 313th meeting and notified vide letter No. F.14-I/2022-PEC dated 14th March 2022.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 75,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

1624.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Biogen Pharmaceuticals 8Km, Chakbeli Road Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has been granted new license (DML No. 000911) by way of formulation dated 13-02-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 14-02-2020 which specifies ampoule section SVP (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27758: 20-10-2020
	Details of fee submitted	PKR 20,000/-: 07-09-2020
	The proposed proprietary name / brand name	**3D Injection 5mg/mL (Oral / IM)**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule Contains: Cholecalciferol……5mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Vitamin D3
	Reference to Finished product specifications	In house specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cholecalciferol Injection **(ANSM** France Approved)
	For generic drugs (me-too status)	Novel-D Injection by Danas Pharma (Reg #073183)
	Name and address of API manufacturer.	Sichuan Yuxin Pharmaceutical Co., Ltd. No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (South District) Shifang city, Sichuan Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against the comparator i.e. Calbon-D Injection 5mg/ml of PDH Laboratories.

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

STABILITY STUDY DATA

Manufacturer of API	Sichuan Yuxin Pharmaceutical Co., Ltd. No. 51, West Section of Changjiang Road, Shifang Economic Development Zone (South District) Shifang city, Sichuan Province China.		
API Lot No.	B-1-51-M191210		
Description of Pack (Container closure system)	Glass ampoule		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T022	T023	T024
Batch Size	500 ampoules	500 ampoules	500 ampoules
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	02-2020	02-2020	02-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Biogen Pharmaceutical is a new License facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML No. 20160429 issued by Sichuan Food and Drug Administration. The certificate is valid till 31-12-2020. The certificate was verified from online database of NMPA website of China (accessed on 25-11-2020).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 2nd February 2020 specifying 50gm vitamin D3. The invoice is not attested by AD (I&E). Firm has submitted copy of DL invoice for import of drug substance.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Shortcoming communicated	Response by the firm
Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method*	Firm has submitted report of verification studies of the analytical method of drug substance

Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".	
Submit COA of reference standard in section 3.2.S.5 as per the guidance document approved by Registration Board which specifies that *"COA of primary / secondary reference standard including source and lot number shall be provided"*	Firm has submitted copy of COA of working standard from API manufacturer.
Justify the formulation without any excipient as submitted in section 3.2.P.1 of module 3.	Firm has submitted master formulation containing excipients.
Justify why pharmaceutical equivalence was performed against the comparator product instead of innovator / reference product.	Firm has submitted that the innovator product was not readily available at the time of performing these studies in Pakistan, therefre we have selected comparator product which is approved by DRAP and is the most running brand of Pakistan for comparative studies.
The analytical method submitted in method validation report submitted in section 3.2.P.5.3 contains HPLC method, while the analytical method submitted in section 3.2.P.5.2 was UV method. Further the results of validation of analytical method specifies the value of absorbance which is based on UV method. Clarification is required in this regard.	Firm has not submitted any clarification in this regard.
Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP.	Firm has submitted copy of commercial invoice dated 2nd February 2020 specifying 50gm vitamin D3. The invoice is not attested by AD (I&E). Firm has submitted copy of DHL invoice for import of drug substance.
Submit copy of batch manufacturing record of 3 stability batches.	Firm has submitted Batch Manufacturing Record of 3 stability batches.

Decision of 297th meeting of Registration Board:
Registration Board deferred the case for rationale of applying UV spectrophotometric method performing Assay analysis of finished drug product for quantification of Vitamin D, whereas the drug substance manufacturer has applied HPLC method for the quantification of Vitamin D in Assay test.

Response by the firm:
Firm has submitted stability study data of 3 newly manufactured batches from the same source using the same already imported API, in which product testing has been performed as per HPLC method. The details of the newly manufactured batches is as under:

Batch No.	T001	T002	T003
Batch Size	1000 ampoules	1000 ampoules	1000 ampoules
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	07-03-2022	07-03-2022	07-03-2022

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit fee of Rs. 30,000 for revision in stability data, change in title of the firm from Biogen Pharmaceuticals to Biogen Life Sciences and pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

Case No. 04 Registration applications of Form-5 cases

a) New cases

1625	**Name and address of manufacturer / Applicant**	**M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Brand Name +Dosage Form + Strength	Biso 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol As Fumarate…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16158: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Actim Tablet by Sami
	GMP status	GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Provide evidence of applied product as film coated tablet in reference regulatory authorities or else revise your formulation to uncoated tablet. • The innovator's product contains bisoprolol fumarate 2.5mg while you have applied for tablet contain bisoprolol as fumarate 2.5mg.
	Decision: Approved with following label claim: Each Tablet Contains: Bisoprolol Fumarate…2.5mg • Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1626	**Name and address of manufacturer / Applicant**	**M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Brand Name +Dosage Form + Strength	Biso 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol As Fumarate…5mg
	Diary No. Date of R& I & fee	Dy No. 16159: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Actim Tablet by Sami
	GMP status	GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • The innovator's product contains bisoprolol fumarate 5mg while you have applied for tablet contain bisoprolol as fumarate 5mg.
	Decision: Approved with following label claim: Each Tablet Contains: Bisoprolol Fumarate…5mg • Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1627	**Name and address of manufacturer / Applicant**	**M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Brand Name +Dosage Form + Strength	Biso 10mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Bisoprolol As Fumarate…10mg
	Diary No. Date of R& I & fee	Dy No. 16160: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Actim Tablet by Sami
	GMP status	GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • The innovator's product contains bisoprolol fumarate 10mg while you have applied for tablet contain bisoprolol as fumarate 10mg.
	Decision: Approved with following label claim: **Each Tablet Contains:** **Bisoprolol Fumarate…10mg** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1628	**Name and address of manufacturer / Applicant**	**M/s Scilife Pharma Pvt Ltd.** **Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Brand Name +Dosage Form + Strength	Cobola 500mcg Tablet
	Composition	Each Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy No. 16161: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Vitamin B12 analogue
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Methycobal tablet by Hilton
	GMP status	GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation to sugar coated tablet as per the reference product along with submission of applicable fee. • You have applied in house specifications while the product monograph is available in JP. Revise your specifications along with submission of applicable fee.
	Decision: Approved with JP Specifications and with following label claim: **Each Sugar Coated Tablet Contains:** **Mecobalamin……500mcg** • **Firm will submit 7,500/- fee for revision of formulation from uncoated to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1629	**Name and address of manufacturer / Applicant**	**M/s Scilife Pharma Pvt Ltd.** **Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Brand Name +Dosage Form + Strength	Valpo 250mg Tablet
	Composition	Each Tablet Contains: Valproate Semi Sodium…269.10mg Eq To 250mg Of Valproic Acid
	Diary No. Date of R& I & fee	Dy No. 16156: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epival Tablet by Abbott
	GMP status	GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • The reference product is available as gastro-resistant tablet while you have applied for simple tablet. Revise your formulation as per reference product along with submission of requisite fee.
	Decision: Approved with USP Specifications and with following label claim: **Each Enteric Coated Tablet Contains:** **Valproate Semi Sodium…269.10mg Eq To 250mg Of Valproic Acid** • **Firm will submit 30,000/- fee for revision of formulation from uncoated tablet to enteric coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1630	**Name and address of manufacturer / Applicant**	**M/s Scilife Pharma Pvt Ltd.** **Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Brand Name +Dosage Form + Strength	Valpo 500mg Tablet
	Composition	Each Tablet Contains: Valproate Semi Sodium…538.20mg Eq To 500mg Of Valproic Acid
	Diary No. Date of R& I & fee	Dy No. 16157: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epival Tablet by Abbott
	GMP status	GMP certificate issued on 17-06-2021 on the basis of inspection conducted on 01-03-2021.
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • The reference product is available as gastro-resistant tablet while you have applied for simple tablet. Revise your formulation as per reference product along with submission of requisite fee.
	Decision: Approved with USP Specifications and with following label claim: **Each Enteric Coated Tablet Contains:** **Valproate Semi Sodium…538.20mg Eq To 500mg of Valproic Acid** • **Firm will submit 30,000/- fee for revision of formulation from uncoated tablet to enteric coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1631	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Aripra Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Aripiprazole…5mg
	Diary No. Date of R& I & fee	Dy No. 14620: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Aripaze Tablet by Global

	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	
1632	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Aripra Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Aripiprazole…10mg
	Diary No. Date of R& I & fee	Dy No. 14621: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Aripaze Tablet by Global
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	
1633	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Aripra Tablet 15mg
	Composition	Each Film Coated Tablet Contains: Aripiprazole…15mg
	Diary No. Date of R& I & fee	Dy No. 14622: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Aripaze Tablet by Global
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	
1634	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Pantozole Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Pantoprazole…40mg
	Diary No. Date of R& I & fee	Dy No. 14615: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Protium Tablet by Abbott
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Pantoprazole (as sodium sesquihydrate).....40mg
	Decision: Approved with following label claim: **Each Enteric Coated Tablet Contains:** **Pantoprazole (as sodium sesquihydrate).....40mg** • **Firm will submit 30,000/- fee for revision of formulation from film coated tablet to enteric coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1635	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Ito safe 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride …50mg
	Diary No. Date of R& I & fee	Dy No. 14618: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiemetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Ganaton Tablet by Abbott
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Itopride HCl……50mg
	Decision: Approved with Innovator's Specifications and with following label claim: **Each Film Coated Tablet Contains:** **Itopride HCl……50mg** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1636	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Ito safe 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Itopride…150mg
	Diary No. Date of R& I & fee	Dy No. 14619: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiemetics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ganaton 150mg Tablet by Abbott
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD

	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1637	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Rabin Tablet 10mg
	Composition	Each Film Coated Tablet Contains: Rabeprazole …10mg
	Diary No. Date of R& I & fee	Dy No. 14623: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Protorib Tablet by Helix
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Rabeprazole sodium …10mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Enteric Coated Tablet Contains:** **Rabeprazole sodium …10mg** • **Firm will submit 30,000/- fee for revision of formulation from film coated tablet to enteric coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1638	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Rabin Tablet 20mg
	Composition	Each Film Coated Tablet Contains: Rabeprazole …20mg
	Diary No. Date of R& I & fee	Dy No. 14624: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Protorib Tablet by Helix
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Rabeprazole sodium …20mg

	Decision: Approved with Innovator's specifications and with following label claim: **Each Enteric Coated Tablet Contains:** **Rabeprazole sodium …20mg** • **Firm will submit 30,000/- fee for revision of formulation from film coated tablet to enteric coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1639	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Clinit Tablet 1mg
	Composition	Each Film Coated Tablet Contains: Cinitapride…1mg
	Diary No. Date of R& I & fee	Dy No. 14616: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Spain Approved
	Me-too status	Cidine 1mg Tablet by Highnoon Laboratories
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Cinitapride as Hydrogen Tartrate……1mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Cinitapride as Hydrogen Tartrate……1mg** • **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1640	**Name and address of manufacturer / Applicant**	**M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi**
	Brand Name +Dosage Form + Strength	Clinit Syrup 1mg/5ml
	Composition	Each 5ml Contains: Cinitapride…1mg
	Diary No. Date of R& I & fee	Dy No. 14617: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Spain Approved
	Me-too status	Cidine Syrup by Highnoon Laboratories
	GMP status	The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator[3].	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each 5ml Contains: Cinitapride as Hydrogen Tartrate……1mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each 5ml Contains:** **Cinitapride as Hydrogen Tartrate……1mg**	

	• **Firm will submit 30,000/- fee for correction in salt form as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1641	**Name and address of manufacturer / Applicant**	**M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Brand Name +Dosage Form + Strength	Levopride 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy No. 16666: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has submitted that their specifications are as per innovator's product.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy approved.
	Me-too status	Levide tablet by Swiss Pharma
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
1642	**Name and address of manufacturer / Applicant**	**M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Brand Name +Dosage Form + Strength	Levopride 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy No. 16667: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has submitted that their specifications are as per innovator's product.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy approved.
	Me-too status	Levide tablet by Swiss Pharma
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)

	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
1643	**Name and address of manufacturer / Applicant**	**M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Brand Name +Dosage Form + Strength	Roso 10mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…10mg
	Diary No. Date of R& I & fee	Dy No. 16664: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Crestat Tablet by CCL
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)
	Remarks of the Evaluator[3].	• Firm has revised the label claim as per the innovator's product along with submission of full fee 30,000/- (vide slip number 23022687538) dated 23-11-2022 as per following: Each Film Coated Tablet Contains: Rosuvastatin (as calcium).….10mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin (as calcium).….10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
1644	**Name and address of manufacturer / Applicant**	**M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Brand Name +Dosage Form + Strength	Roso 20mg Tablet
	Composition	Each Tablet Contains: Rosuvastatin…20mg
	Diary No. Date of R& I & fee	Dy No. 16665: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Crestat Tablet by CCL
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional

		sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)
	Remarks of the Evaluator[3].	• Firm has revised the label claim as per the innovator's product along with submission of full fee 30,000/- (vide slip number 48933741286) dated 23-11-2022 as per following: Each Film Coated Tablet Contains: Rosuvastatin (as calcium).…20mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin (as calcium).…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
1645	**Name and address of manufacturer / Applicant**	**M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Brand Name +Dosage Form + Strength	Q-Formin 1/500 mg Tablet
	Composition	Each Tablet Contains: Glimepiride…1mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16662: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Sulfonylureas + Biguanides
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Getformin Tablet by Getz
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)
	Remarks of the Evaluator[3].	

Shortcomings communicated	**Response by the firm**
Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting	Firm has requested to revise their formulation as per the following label claim along with submission of revised form 5 along with annexures. Firm has also submitted complete fee 30,000/- vide slip number 6483484697 dated 23-11-2022. The newly applied product composition is as under: Each tablet contains: Glimepiride…….. 2mg

	Decision: Approved with following label claim: **Each tablet contains:** **Glimepiride…….. 2mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
1646	**Name and address of manufacturer / Applicant**	**M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Brand Name +Dosage Form + Strength	Q-Formin 2/500 mg Tablet
	Composition	Each Tablet Contains:

		Glimepiride…2mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16663: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Sulfonylureas + Biguanides
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Getformin Tablet by Getz
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section 3. R&D laboratory 4. Sachet (general)

Remarks of the Evaluator[3].

Shortcomings communicated	**Response by the firm**
Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting	Firm has requested to revise their formulation as per the following label claim along with submission of revised form 5 along with annexures. Firm has also submitted complete fee 30,000/- vide slip number 48024336 dated 23-11-2022. The newly applied product composition is as under: Each tablet contains: Glimepiride…….. 4mg

Decision: Approved with following label claim:

Each tablet contains:

Glimepiride…….. 4mg

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

1647	**Name and address of manufacturer / Applicant**	**M/s Quaper Pharmaceuticals Plant 26-A Small Industrial Esatte Lahore Road Sargodha**
	Brand Name +Dosage Form + Strength	Glimacorn 80mg Tablet
	Composition	Each Tablet Contains: Gliclazide…80mg
	Diary No. Date of R& I & fee	Dy No. 16661: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Diamicron Tablet by Servier
	GMP status	Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General). Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan: 1. Tablet (General) section 2. Capsule (general) section

		3. R&D laboratory 4. Sachet (general)
	Remarks of the Evaluator[3].	
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	

a) Deferred cases

1648.	**Name and address of manufacturer / Applicant**	**M/s Wilson's Pharmaceuticals, 387- 388, I-9 Industrial Area, Islamabad.**
	Brand Name +Dosage Form + Strength	Talergin EB Syrup
	Composition	Each ml contains: Ebastine ….....5mg
	Diary No. Date of R& I & fee	Dy.No.2179;26-02-2018; Rs.20,000/- (26-02-2018)
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30ml & 60ml / bottle & as per SRO
	Approval status of product in Reference Regulatory Authorities	**Could not be confirmed**
	Me-too status	Fystine Liquid Syrup of M/s Fynk Pharma (Reg. # 077173)
	GMP status	Last GMP inspection was conducted on 24-01-2018 and the report concludes very good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has Oral Liquid General Section as mentioned in the GMP inspection report. • No USP, BP or JP monograph is available for the applied formulation. • Internationally, the applied formulation could not be confirmed.
	Decision of 288th meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Response by the firm: Firm has submitted evidence of following product: **Name:** Ebastel 1 mg/ml oral solution **Label claim:** Each ml of oral solution contains 1 mg ebastine. **RRA:** CIMA Spain. • As per RRA approved product the firm contains 1mg ebastine/ml while as per the minutes of 288th meeting of RB the label claim is 5mg ebastine/ml. Firm in its covering letter (Dy No. 33801 dated 23-11-2022) have submitted that they have applied for 1mg ebastine/ml and it was typo error in the minutes of 288th meeting of RB. Firm has also submitted copy of covering letter stamped by statistical officer with endorsement of 20,000 fee dated 28-02-2018 and R&I stamp dated 28-02-2018 which specifies ebastine 5mg/5ml. • Firm has also submitted an undertaking on stamp paper that the applied product composition was ebastine 5mg/5ml.	
	Decision: Approved with Innovator's specifications and with following label claim: **Each 5ml contains:** **Ebastine ….....5mg** • **Firm will submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

1649.	Name and address of Applicant	M/s OBS Pakistan (Pvt.) Limited, C-14, Manghopir Road, S.I.T.E, Karachi- 75700, Pakistan
	Detail of Drug Sale License	Drug License by way of Wholesale No. 0950 valid upto 26-03-2021
	Manufacturer & Product License Holder:	Manufacturer: M/s Santen Pharmaceutical Co., Ltd. Noto Plant: Manufacturing site: 2-14, Shikinami Hodatsushimizu-Cho Hakui-Gun, Ishikawa, Japan Corporate office address: 9-19, Shimoshinjo 3-chome, Higashiyodogawa-ku, Osaka, Japan
	Name of exporting country	Japan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 3777 Dated 30-01-2018
	Fee including differential fee	Rs. 100,000/- Dated 30-01-2018
	Brand Name +Dosage Form + Strength	Hyalein Ophthalmic Solution 0.1% w/v
	Composition	Each ml contains: Purified Sodium Hyaluronate ……1mg
	Finished Product Specification	JP
	Pharmacological Group	Artificial tears
	Shelf life	36 Months
	Pack size & Demanded Price	1's (5ml) & As per SRO
	International availability	Japan
	Me-too status	Not available
	Stability studies	Firm has submitted long term (36 months) at $30^{o}C \pm 2^{0}C$, 75%RH±5%RH & accelerated (06 months) stability data at $40^{o}C$, 75% RH for three batches.
	Detail of certificates attached	• Original Legalized CoPP (Certificate#. 2503) issued on 23-08-2017 by Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare 2-2, Kasumigaseki 1-chome, Chiyoda-ku Tokyo declaring the free sale of applied product and GMP compliant status of the manufacturer. • Original product Specific Sole agency agreement from product License Holder is submitted.
	Remarks of the Evaluator.	
	Decision of 293rd meeting: Deferred for clarification regarding pharmaceutical or medical device nature of applied product. Submission by the firm: The firm has provided following references where the applied product is registered as drug. • Hialid 0.1 approved in Hongkong • Hyalein 0.1 approved in Korea • Hialid 0.1 by M/s Santen Pharmaceutical Co., Ltd., Myanmar Approved. • Hialid 0.1 Approved in Philipines. The references provided by the firm could not be confirmed as well as the approval status of the applied product as drug in RRAs could not be confirmed. Decision of 297th meeting:	

The Board deferred the case for clarification regarding pharmaceutical or medical device nature of applied product.
Submission by the firm:
The firm has provided following reference.
1. Hyalein eye drops (0.1% and 0.3%) mfg by M/s Santen Pharmaceutical Co., Ltd, Japan.
The screen short of composition from the translated (by google translate) Interview form is given in the following.

Eye drops for the treatment of keratoconjunctival epithelial disorders

Japanese Pharmacopoeia **Purified Sodium Hyaluronate Ophthalmic Solution**

**** [Composition / Properties]**

Sales name	Hyalein Eye drops 0.1 %	Hyalein Eye drops 0.3 %	Hyalein Mini eye drops 0.1%	Hyalein Mini eye drops 0.3%
Effective	Purified sodium hyaluronate			
Content (in 1 mL)	1 mg	3 mg	1 mg	3 mg
Additive	Epsilon-Aminoca Proic acid, edetate na Thorium hydrate, professional Pyrene glycol, salt Sodium chemicals, chlor Hexidine gluconic acid Salt solution, pH regulator		Epsilon-Aminoca Proic acid, edetate na Thorium hydrate, chloride Potassium, Natri Chloride Umm, pH regulator	
pH	6.0-7.0			
Permeation ratio	0.9-1.1			

https://www.pmda.go.jp/PmdaSearch/iyakuDetail/ResultDataSetPDF/300237_1319720Q3078_1_15 (Accessed on 31/05/2021)
https://www.pmda.go.jp/PmdaSearch/iyakuSearch/ (Accessed on 31/05/2021)

Decision of 308th meeting of Registration Board:
The Board after thorough discussion deferred the case for further deliberation for deciding whether the applied product falls under category of Medical Device or Pharmaceutical Drug. Opinion of MDMC Division will also be taken for status of product as per Medical Device Rules.

Evaluation by PEC:
As per the decision of 308th meeting of Registration Board, the case was forwarded to MDMC Division through e-office file number 7-1/2019-PEC. The response of the MDMC Division is placed below:

Reference pre paras, the undersigned searched the GMDN Agency for the said case, and the molecule/formulation 0.1% w/v Sodium Hyaluronate solution is not found in it.
Furthermore, after examination of the case as per the attached documents and provided online link, it is submitted that:-

i. *the intended use of the product as per manufacturer's claim is for the treatment of Keratoconjuctival epithelial disorder and the mechanism of action is that it promotes corneal injury healing by binding to fibronectin and promoting adhering/repairing corneal epithelial cells and not just physiological action.*
ii. *Also the product is a drug in the country of origin i.e. Japan which is one of the stringent regulatory authorities.*

	Therefore, in the light of above stated position, it is proposed that the case may be dealt under the existing rules pertaining to drug.
	Decision: Registration Board after thorough deliberation and considering the response of the MDMC Division and the fact that the applied product is approved as a drug product by PMDA Japan which is a reference regulatory authority, decided to approve the applied product as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

Agenda of Evaluator PEC-IV

Case no. 01 Registration applications for local manufacturing of (Human) drug (Form 5F)

a. New cases

1650.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt) Ltd. Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt) Ltd. Plot #129 Sundar Industrial Estate,Raiwind road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32417 dated 29-11-2021
	Details of fee submitted	PKR 30,000/-: Deposit slip # 080629654
	The proposed proprietary name / brand name	**Mavinate 50mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Dimenhydrinate…….50mg
	Pharmaceutical form of applied drug	Almost white coloured round plain tablet
	Pharmacotherapeutic Group of (API)	Anti Histamine agent
	Reference to Finished product specifications	BP
	Proposed Pack size	10×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dimenhydrinate of MHRA approved.
	For generic drugs (me-too status)	Dymin 50mg tablet by M/s Stanley Pharmaceuticals, Reg. No. 001924
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of evaluation conducted on 08-09-2021
	Name and address of API manufacturer.	M/s S.S Pharmachem,India K-44/45, M.I.D.C. Tarapur, Biosar, Dist. Phalghar Thane, Maharashtra,India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's,, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Dimenhydrinate is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility's,, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (SAM/DMN/001, SAM/DMN/002, SAM/DMN/003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that Gravinate 50mg tablet by M/s Searle company Lahore (Batch # B0213) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Gravinate 50mg tablet by M/s Searle company Lahore in Acid media (pH-1.2),Acetate Buffer(pH-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s S.S Pharmachem,India K-44/45, M.I.D.C. Tarapur, Biosar, Dist. Phalghar Thane, Maharashtra, India.
API Lot No.	SAM/DMN/0520014
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10×10's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TDM002	TDM003	TDM004
Batch Size	2000 tab	2000 tab	2000 tab
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	02-02-2021	06-02-2021	10-02-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 6107563 issued by Food and drug Adminstration (Maharashtra State) India valid till 29/06/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form 3, form 7 , invoice (invoice# 09/2020-21) dated 25-07-2020 cleared by DRAP Lahore office dated 28-08-2020 specifying import of Dimenhydrinate 100 Kg (Batch# SAM/DMN/0520014).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm submitted assay method by titration as mentioned in B.P monograph.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Good Manufacturing Practice (GMP) certificate submitted.
2.	3.2.P.2.2.1	Details of product against which Pharmaceutical Equivalence and CDP was conducted.	Gravinate 50mg tablet Batch No # 0213 manufactured by M/s Searle company Lahore
3.	3.2.P.5.2	Method for Dissolution test not submitted.	Method for dissolution submitted.
4.	3.2.P.4.4	Dissolution test not conducted.	Dissolution test are included in COA's
5.	3.2.P.8	• Dissolution is not conducted through out	• Stability studies with dissolution test are submitted

		the stability studies. Clarification is required. • All the test specified in specifications are not in conducted in stability studies. Clarification is required. • In Stability studies summary sheets film coated tablet written while applied formulation is uncoated tablet.	• Complete COA with all test are attached. • It was typographical error and stability summary sheets after correction are attached. Our product is uncoated tablet.

Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.

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

Case no. 02 Registration applications for local manufacturing of (Human) drug (Form 5)

a. New cases

1651.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	IPS Syrup
	Composition	Iron Protein Succinylate 800mg Eq. to Elemental Iron…40mg Folic Acid…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 14294 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antianemic preparations
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	60ml, 120ml :As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Not found
	GMP status	Copy of GMP certificate No. F.3-55/2020-Addl.Dir.(QA&LT-1) issued on the basis of inspection conducted on12/08/2020.
	Remarks of the Evaluator	Firm change formulation as follows Each 15ml contains: Iron Protein Succinylate 800mg Eq. to Elemental Iron…40mg Folic Acid…5mg With submission of fee of Rs: 5000/- deposit slip No# 2017947, Dated: 03-08-2020 Sucrofer-F Syrup. Of M/s CCL Pharmaceuticals (Reg# 057525)
	Decision: Approved with innovator's specification as following label claim: "Each 15ml contains: Iron Protein Succinylate 800mg Eq. to	

	Elemental Iron…40mg **Folic Acid…5mg"** • **Firm shall submit the differential fee of Rs. 25,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1652.	Name and address of manufacturer / Applicant	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Brand Name +Dosage Form + Strength	Valet 200mg/5ml Dry Suspension
	Composition	Each 5ml Suspension after Reconstitution Contains: Voriconazole…200mg
	Diary No. Date of R& I & fee	Dy.No. 40912 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Anti fungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	30ml, 60ml, 75 ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	VFEND 200 mg/5ml Oral Suspension of (USFDA approved)
	Me-too status	Vorif Dry Suspension of M/s Ferozsons Labs
	GMP status	GMP certificate issued on basis of inspection conducted on 25-11-2022
	Remarks of the Evaluator Shortcomings communicated: Reply Revise master formulation in terms of quantity of Voriconazole per bottle.: Firm revised their formulation in terms of quantity of Voriconazole as per reference regulatory authority product with submission of fee of Rs: 30000/- deposit slip # 75276165 dated: 29-09-2022	
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1653.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Mebra 25/5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Metoprolol tartrate…25mg Ivabradine as Hcl Eq. to Ivabradine…5mg
	Diary No. Date of R& I & fee	Dy.No. 9899 dated 04-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Beta blocking agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	7's, 14's, 28's & 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Implicor Tablets 25mg/5mg of SERVIER LABORATORIES of ANSM approved.
	Me-too status	Implicor Tablets 25mg/5mg of M/s servier Research & pharmaceuticals Reg# 099004
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an

		acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	• Evidence of SRA and mee-too status provided.
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1654.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Mebra 50/5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Metoprolol tartrate…50mg Ivabradine as Hcl Eq. to Ivabradine…5mg
	Diary No. Date of R& I & fee	Dy.No. 9897 dated 04-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Beta blocking agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	7's, 14's, 28's & 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	IMPLICOR 50 mg / 5 mg of ANSM france approved
	Me-too status	Implicor Tablets 50mg/5mg of M/s servier Research & pharmaceuticals Reg# 099006
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Evidence of mee-too status provided.
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1655.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Mebra 50/7.5 mg Tablet
	Composition	Each Film Coated Tablet Contains: Metoprolol tartrate…50mg Ivabradine as Hcl Eq. to Ivabradine…7.5mg
	Diary No. Date of R& I & fee	Dy.No. 9898 dated 04-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Beta blocking agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	7's, 14's, 28's & 30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	IMPLICOR 50 mg /7.5 mg of ANSM france approved
	Me-too status	Implicor Tablets 50mg/7.5mg of M/s servier Research & pharmaceuticals Reg# 099495
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Evidence of mee-too status provided.
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1656.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan

	Brand Name +Dosage Form + Strength	Indap 10/2.5/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Perindopril Argenine…10mg Indapamide…2.5mg Amlodipine as Besylate…10mg
	Diary No. Date of R& I & fee	Dy.No. 9892 dated 04-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	30, 60;s :As per SRO
	Approval status of product in Reference Regulatory Authorities	Coverdine 5mg/2.5mg/10mg film-coated tablets of HPRA Ireland approved
	Me-too status	Triplixam tablet 10mg/2.5mg/10mg of servier Research & pharmaceuticals Reg# 093939
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Evidence of mee-too status provided.
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1657.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Brand Name +Dosage Form + Strength	Angest 500/160/267 mg Oral Suspension
	Composition	Each 10ml Contains: Sodium Alginate…500mg Calcium Carbonate…160mg Sodium bicarbonate…267mg
	Diary No. Date of R& I & fee	Dy.No. 10516 dated 05-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	60ml, 90ml. 120ml, :As per SRO
	Approval status of product in Reference Regulatory Authorities	Gaviscon Cool Mint Liquid of MHRA approved
	Me-too status	Gaviscon 500mg/160mg/267mg of M/s Reckitt Benkiser Healthcare Reg # 016024
	GMP status	Last inspection was conducted on 10-04-2019 and report concludes that firm is operating at an acceptable level of cGMP compliance.
	Remarks of the Evaluator [IV]	Evidence of mee-too status provided.
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	

Case no. 03 Registration applications of newly granted DML or New section (Human)

a. New DML

i. New Cases

1658.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24366 dated 29-08-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 4196848406
	The proposed proprietary name / brand name	Fleclox 250 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Ampicillin as Ampicillin trihydrate …..125 mg Cloxacillin as Cloxacillin Sodium….125 mg
	Pharmaceutical form of applied drug	Black cap and red body Capsule shell #2 filled with white to off white powder.
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	20 x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not found
	For generic drugs (me-too status)	Ampilcox Capsules by M/s GSK, Reg. No. 000181
	GMP status of the Finished product manufacturer	New DML letter issued dated; 14-09-2021
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.
	Remarks of Evaluator: Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board could not be found so data have not been evaluated. Communicated to firm Dated: 15th September, 2022 but still no reply from firm received.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1659.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24367 dated 29-08-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 049390998156
	The proposed proprietary name / brand name	Fleclox 500 mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Ampicillin as Ampicillin trihydrate …..250 mg Cloxacillin as Cloxacillin Sodium….250 mg
	Pharmaceutical form of applied drug	Black cap and red body Capsule shell #2 filled with white to off white powder.
	Pharmacotherapeutic Group of (API)	Penicillin antibiotic
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	20 x 5's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not found
	For generic drugs (me-too status)	Ampilcox Capsules by M/s GSK, Reg. No. 000182
	GMP status of the Finished product manufacturer	New DML letter issued dated; 14-09-2021
	Name and address of API manufacturer.	M/s Pharmagen Limited Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.
	Remarks of Evaluator: Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board could not be found so data have not been evaluated. Communicated to firm Dated: 15th September, 2022 but still no reply from firm received.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

M/s AJM Pharma Pvt Ltd. Karachi:

The Authority, keeping in view the decision of the Appellate Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd, Karachi to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of A.J. Mirza Pharma (Pvt) Ltd, Karachi.

Following Products are already Registered products:

1660.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R& I & fee	Dy.No. 34637 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip #2763746716
	Pharmacological Group	Antiepileptic

	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica 50mg of (USFDA approved)
	Me-too status	Gabica 50mg Capsule by M/s Getz Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Firm claimed USP specification while Pregabalin capsule monograph is not available in any pharmacopeia.
	Decision: Approved with BP specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1661.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip 75mg Capsule
	Composition	Each Capsule Contains: Pregabalin…75mg
	Diary No. Date of R& I & fee	Dy.No. 34638 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip #17493298
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica 75mg of (USFDA approved)
	Me-too status	Gabica 75mg Capsule by M/s Getz Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Firm claimed USP specification while Pregabalin capsule monograph is not available in any pharmacopeia
	Decision: Approved with BP specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1662.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy.No. 34636 30-11-2022 Rs.30,000/- dated

		17-11-2022 Deposit slip #2405355284
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica 100mg of (USFDA approved)
	Me-too status	Gabica 100mg Capsule by M/s Getz Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Firm claimed USP specification while Pregabalin capsule monograph is not available in any pharmacopeia.
	Decision: Approved with BP specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1663.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip 150mg Capsule
	Composition	Each Capsule Contains: Pregabalin…150mg
	Diary No. Date of R& I & fee	Dy.No. 34634 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip #8973545966
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica 150mg of (USFDA approved)
	Me-too status	Gabica 150mg Capsule by M/s Getz Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Firm claimed USP specification while Pregabalin capsule monograph is not available in any pharmacopeia.
	Decision: Approved with BP specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1664.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip 300mg Capsule
	Composition	Each Capsule Contains:

		Pregabalin…300mg
	Diary No. Date of R& I & fee	Dy.No. 34635 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip #9836952834
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica 300mg of (USFDA approved)
	Me-too status	Gabica 300mg Capsule by M/s Getz Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Firm claimed USP specification while Pregabalin capsule monograph is not available in any pharmacopeia.
	Decision: Approved with BP specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1665.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajprazole 20mg Capsule
	Composition	Each Capsule Contains: Esomeprazole Magnesium Trihydrate (enteric coated pellets) Eq. to Esomeprazole…20mg
	Diary No. Date of R& I & fee	Dy.No. 34624 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 0651582061
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2×7's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium 20 mg for capsule Of (USFDA Approved)
	Me-too status	Esomap Capsules 20mg by M/s Efroze Chemical
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Submit following: Source of pellets

		GMP certificate of source of pellets Stability study of 3 batches of pellets Certificate of analysis of pellets.
	Decision: Approved. Firm shall submit documents for source of pellets along with GMP certificate, COA, stability studies of three batches & differential fee (in case of import).	
1666.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajprazole 40mg Capsule
	Composition	Each Capsule Contains: Esomeprazole Magnesium Trihydrate (enteric coated pellets) Eq. to Esomeprazole…40mg
	Diary No. Date of R& I & fee	Dy.No. 34625 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 88112875257
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2×7's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium 40 mg for capsule Of (USFDA Approved)
	Me-too status	Esomap Capsules 40mg by M/s Efroze Chemical
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Submit following: Source of pellets GMP certificate of source of pellets Stability study of 3 batches of pellets Certificate of analysis of pellets.
	Decision: Approved. Firm shall submit documents for source of pellets along with GMP certificate, COA, stability studies of three batches & differential fee (in case of import).	
1667.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajsuloc SR 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulosin Hcl……..0.4mg (Modified Release Pellets)
	Diary No. Date of R& I & fee	Dy.No. 34643 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 78317526
	Pharmacological Group	Alpha blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Contiflo xl capsule of (MHRA approved)

	Me-too status	Alfamax tablet M/s Platinum Pharmaceuticals,
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Submit following: Source of pellets GMP certificate of source of pellets Stability study of 3 batches of pellets Certificate of analysis of pellets.
	Decision: Approved. Firm shall submit documents for source of pellets along with GMP certificate, COA, stability studies of three batches & differential fee (in case of import).	
1668.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Geftapin 300mg Capsule
	Composition	Each Capsule Contains: Gabapentin…300mg
	Diary No. Date of R& I & fee	Dy.No. 34626 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 300748088108
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1×10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	NEURONTIN capsule 300mg Of (USFDA Approved)
	Me-too status	Abapen Capsule 300mg by M/s Bosch Pharmaceuticals
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	
	Decision: Approved with USP specification.	
	Following Products are approved in various meetings but registration letters were not issued:	
1669.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Geftapin 100mg Capsule
	Composition	Each Capsule Contains: Gabapentin…100mg

	Diary No. Date of R& I & fee	Dy.No. 34668, 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 65211747432
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1×10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	NEURONTIN capsule 100mg Of (USFDA Approved)
	Me-too status	Abapen Capsule 100mg by M/s Bosch Pharmaceuticals
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	The case was previously approved in 291st meeting of Registration Board with brand name of "Gabitin capsule"
	Decision: Approved with USP specification.	
1670.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Elox 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Levofloxacin as Levofloxacin Hemihydrate…250mg
	Diary No. Date of R& I & fee	Dy.No. 34679 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 972662850
	Pharmacological Group	Antibiotics (Fluoroquinolones)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Evoxil 250 mg film-coated tablets by M/s Beacon Pharm (MHRA approved)
	Me-too status	Leoflox 250mg Tablet by M/s Bryon Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)

	Remarks of the Evaluator [IV]	The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with USP specification.	
1671.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Elox 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Levofloxacin as Levofloxacin Hemihydrate…500mg
	Diary No. Date of R& I & fee	Dy.No. 34675 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 475806758
	Pharmacological Group	Antibiotics (Fluoroquinolones)
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Evoxil 500 mg film-coated tablets by M/s Beacon Pharm (MHRA approved)
	Me-too status	Leoflox 500mg Tablet by M/s Bryon Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with USP specification.	
1672.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Larilid 250mg Tablet
	Composition	Each Tablet Contains: Clarithromycin…250mg
	Diary No. Date of R& I & fee	Dy.No. 34680 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 9714066453
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Klaricid of (MHRA approved)
	Me-too status	Respect tablet M/s Spencer Pharmaceutical
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General)

		4. Dry Powder (General)
	Remarks of the Evaluator [IV]	• In label claim uncoated tablet mentioned while reference products is film coated. • In master formulation film coating excipients are mentioned but in manufacturing method step of coating not included. • Specifications are not mentioned • The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with USP specification. **Firm shall submit fee of Rs.7,500 for correction/pre-approval change product specifications, and change in composition (correction/change of formulation from un-coated tablet to film coated tablet) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1673.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Larilid 500mg Tablet
	Composition	Each Tablet Contains: Clarithromycin…500mg
	Diary No. Date of R& I & fee	Dy.No. 34666 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 1155017375
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Klaricid of (MHRA approved)
	Me-too status	Respect tablet M/s Spencer Pharmaceutical
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	• In label claim uncoated tablet mentioned while reference products is film coated. • In master formulation film coating excipients are mentioned but in manufacturing method step of coating not included. • Specifications are not mentioned • The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with USP specification. Firm shall submit fee of Rs.7,500 for correction/pre-approval change product specifications, and change in composition (correction/change of formulation from un-coated tablet to film coated tablet) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1674.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ormol 35/450 mg Tablet

	Composition	Each Tablet Contains: Orphenadrine Citrate…35mg Paracetamol…450mg
	Diary No. Date of R& I & fee	Dy.No. 34682 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 65558988244
	Pharmacological Group	Analgesic, anti-pyretics, muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	
	Pack size & Demanded Price	10×10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic by M/s iNova Pharmaceuticals, Australia(TGA)
	Me-too status	SIC Tablets of M/s Shrooq Pharmaceuticals
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	• Specifications are not mentioned • The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1675.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajglip 3 mg Tablet
	Composition	Each Tablet Contains: Glimepiride…….3mg
	Diary No. Date of R& I & fee	Dy.No. 34673 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 194616272
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Glimepiride 3mg tablets of MHRA approved
	Me-too status	Leadryl 3mg tablet of M/ Leads Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	The case was previously approved in 296th meeting of Registration Board.
	Decision: Approved with USP specification.	

1676.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajglip 4 mg Tablet
	Composition	Each Tablet Contains: Glimepiride…….4mg
	Diary No. Date of R& I & fee	Dy.No. 34667 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 53698046776
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Glimepiride 4mg tablets of MHRA approved
	Me-too status	Leadryl 4 mg tablet of M/ Leads Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	The case was previously approved in 296th meeting of Registration Board.
	Decision: Approved with USP specification.	
1677.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Clodip 75mg Tablet
	Composition	Each Film Coated Tablet Contains: Clopidogrel Bisulphate 97.9mg Eq. to Clopidogrel…75mg
	Diary No. Date of R& I & fee	Dy.No. 34681 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 074030880089
	Pharmacological Group	Platelet aggregation inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Plavix 75mg of (USFDA approved)
	Me-too status	Clorel 75mg tablet of M/s Mission
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	The case was previously approved in 292nd meeting of Registration Board.
	Decision: Approved with USP specification.	
1678.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan

	Brand Name +Dosage Form + Strength	Solin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…5mg
	Diary No. Date of R& I & fee	Dy.No. 34677 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 8264419575
	Pharmacological Group	Muscarinic Antagonist
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	1 x 10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	VESICARE 5 mg of MHRA approved.
	Me-too status	Solifen 5mg Tablet by M/s Getz Pharmaceuticals, Karachi
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with USP specification.	
1679.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…10 mg
	Diary No. Date of R& I & fee	Dy.No. 34678 30-11-2022 Rs.30,000/- dated 16-11-2022 Deposit slip # 186918900054
	Pharmacological Group	Muscarinic Antagonist
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications.
	Pack size & Demanded Price	1 x 10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	VESICARE 10 mg of MHRA approved.
	Me-too status	Solifen 10mg Tablet by M/s Getz Pharmaceuticals, Karachi.
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with USP specification.	
1680.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajnap 250 mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Naproxen Base 250mg Eq. to Naproxen Sodium…275mg
	Diary No. Date of R& I & fee	Dy.No. 34674 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 8743901438
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status	Rokflex 250 mg Tablets of M/s Rock Pharmaceuticals Laboratories, (Pvt) Ltd Reg # 077306
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	In reference product (Health Canada and TGA) Naproxen sodium 275 mg available and no equivalency is mentioned while 250mg Tablet Contains only Naproxen as API not in salt form (on challan Naproxen 250 mentioned) The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved as per following label claim: **"Each Tablet Contains:** **Naproxen ……. 250mg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product compositions as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1681.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajnap 250 mg Tablet
	Composition	Each Film Coated Tablet Contains: Naproxen Base 500mg Eq. to Naproxen Sodium…550mg
	Diary No. Date of R& I & fee	Dy.No. 34674 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 186918900054
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status	Rokflex 500 mg Tablets of M/s Rock Pharmaceuticals Laboratories, (Pvt) Ltd Reg # 077307
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation

		for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	In reference product (Health Canada,TGA and USFDA) Naproxen sodium 550 mg available and no equivalency is mentioned while 500mg Tablet in Contains only Naproxen as API not in salt form (on challan Naproxen 550 mentioned) The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved as per following label claim: **"Each Tablet Contains:** **Naproxen ……. 500mg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product compositions as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1682.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zelotrine 5mg Tablet
	Composition	Each Tablet Contains: Levocetirizine Dihydrochloride…5mg
	Diary No. Date of R& I & fee	Dy.No. 34669 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 19990085911
	Pharmacological Group	Anti-Histamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1×10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Levocetirizine tablets by Actavis (MHRA Approved)
	Me-too status	Invocet tablet by Aries Pharma
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	• In label claim uncoated tablet mentioned while reference products is film coated.(master formulation and manufacturing method included coating step) • The case was previously approved in 296th meeting of Registration Board.
	Decision: Approved with USP specification. Firm shall submit fee of Rs.7,500 for correction/pre-approval change change in composition (correction/change of	

	formulation from un-coated tablet to film coated tablet) as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1683.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Dota-J 40mg Tablet
	Composition	Each Tablet Contains: Drotaverine Hcl……40mg
	Diary No. Date of R& I & fee	Dy.No. 34670 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 82214275804
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in three EMA states tablets in Hungary Romania & Solvakia
	Me-too status	Spasmostar Tablets. Of M/s Star Laboratories Reg. No. 78711
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	Specifications not mentioned. • The case was previously approved in 293rd meeting of Registration Board.
	Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1684.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Ajquine 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No. 34672 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 5032805299
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Hydroxychloroquine Sulfate Tablets 200mg approved by US-FDA
	Me-too status	HCQ 200 Tablets 200mg (Reg. No.: 045471) of M/s Getz Pharma Industrial Area, Karachi.
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug

		manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	In master formulation coating material is not mentioned. • The case was previously approved in 295th meeting of Registration Board.
	Decision: Approved with USP specification. Firm shall submit fee of Rs.7,500 for correction/pre-approval change in the master formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1685.	Name and address of manufacturer / Applicant	M/s AJM Pharma Pvt Ltd. Plot No. 44, Sector No. 27, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zelotrine 2.5mg/5ml Syrup
	Composition	Each 5ml Contains: Levocetirizine Dihydrochloride…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 34671 30-11-2022 Rs.30,000/- dated 17-11-2022 Deposit slip # 87574608101
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specifications	
	Pack size & Demanded Price	30ml, 60ml, 120ml ;As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL (levocetirizine dihydrochloride) oral solution 0.5mg/ml. USFDA approved
	Me-too status	T-Day Syrup 2.5mg/5ml. Reg. No. 83990
	GMP status	Last inspection conducted on 22 -08-2022 and report concludes that panel Unanimously recommends the re-grant of drug manufacturing license by way of formulation for following sections: 1. Tablet (General) 2. Capsule (General) 3. Liquid Syrup (General) 4. Dry Powder (General)
	Remarks of the Evaluator [IV]	• Pharmacological group mentioned as Antipsychotic. • Applied USP specification while monograph not available in any pharmacopeia. • The case was previously approved in 296th meeting of Registration Board.
	Decision: Approved with innovator's specification. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, and Pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	

ii. Deferred case of New DML

1686.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swera Pharmaceuticals. Plot No. 27, Street No. S-4, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals. Plot No. 27, Street No. S-4 National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2365 dated 25-01-2022
	Details of fee submitted	PKR 30,000/-: Deposit Slip No# 64944411
	The proposed proprietary name / brand name	**Login 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Diclofenac Sodium (as 32% Enteric coated pellets)…50mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Non steroidal anti inflammatory Drugs
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	2 x 10's , 3 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Difene 50mg Capsules of Ireland approved
	For generic drugs (me-too status)	Diclogesic 50mg Capsule by Wilson Pharmaceuticals Reg. No. 011892
	GMP status of the Finished product manufacturer	New DML letter issued dated; 16-09-2021
	Name and address of API manufacturer.	Vision Pharmaceuticals (pvt) Ltd Plot3 22-23, Industrial Triangle, Kahutta road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification

		studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Mobikare 50mg Capsule. By M/s Barret Hodgson by performing quality tests (Identification, Assay, and dissolution). Firm has performed comparative dissolution profile against the product i.e Mobikare by M/s Barret Hodgson Batch No# C8862, Pakistan in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8). and the results are within acceptable limit
	Analytical method validation/verification of product	Method Validation have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot# 22-23, Industrial Triangle, Kahutta road, Islamabad.	
API Lot No.	DE931	
Description of Pack (Container closure system)	PVC Blistering	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	TB-C001	TB-C002
Batch Size	5000 Capsules	5000 Capsules
Manufacturing Date	10-2021	10-2021
Date of Initiation	08-10-2021	08-10-2021
No. of Batches	02	

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	New section
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad. It is valid till 10-02-2022.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice No # 801689 dated: 16-09-2021 specifying 2 Kg of Diclofenac sodium 32% EC pellets batch no # DE931
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches have been submitted by UV method along with respective documents like COA, summary data, sheets.
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has performed testing of Login 50mg capsule on UV spectrophotometer
18.	Record of Digital data logger for temperature and humidity monitoring of	Submitted

	stability chambers (real time and accelerated)	

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	2.3.R.1.1	Quantity of Pellets subject to assay and moisture content not calculated, clarification is required	Assay is done on 'as is basis' so there is no need of calculation of moisture content.
2.	2.3.R.1.2	Provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product.	Submitted
3.	3.2.P.2.2.1	Pharmaceutical equivalence of the applied drug shall be established with the innovator product and results of all the quality tests of the developed formulation and the innovator product shall be submitted and discussed.	We were unable to arrange the innovator product that's why we couldn't perform Pharmaceutical equivalence against the innovator product. Pharmaceutical equivalence of Login capsules has been performed against Mobikare capsules prepared by Barret Hodgson as per available guidance document on dra website i.e Pharmaceutical equivalence may also be carried out against reference/comparator product.
4.	3.2.P.5.2	• Justification is required for performing assay testing by UV method instead of HPLC method. • Justification is required for setting dissolution limit in phosphate buffer stage as NLT 75% in 45 min which is different from that mentioned in Specifications i.e., NLT 75% in 30 min.	• The assay was performed on UV Spectrophotometer as the method provided by the Diclofenac sodium pellets manufacturer was also on UV, moreover complete method validation has been performed and submitted for your kind consideration. • The dissolution time limit is 45 minutes, the time 30 minutes is typographical error.
5.	3.2.P.5.3	Submit protocols of analytical method validation.	Submitted
6.	3.2.P.8	• Documents for the procurement of the API including purchase invoice from M/s Vision Pharmaceuticals (Pvt.) Ltd. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Submitted • Submitted

Previous Decision (M-320): The Board deferred the case for scientific justification of performance of assay testing by using UV-spectrophotometer instead of using HPLC method as performed by the reference product.

Reply of firm: For Login 5mg capsules the UV Spectrophotometry was used as in British Pharmacopoeia 2020 Diclofenac sodium Prolong Release Capsule are tested on UV spectrophotometer. The specimen of British pharmacopoeia Diclofenac sodium prolong release capsules is attached. Moreover the supplier also used the same UV spectrophotometric method for testing of pellets**.**

Decision: Approved with innovator's specification.

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

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

Case no. 04 Registration applications of import cases

a. New Cases (Human)

1687.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt.) Ltd. Ground Floor,6- Judicial Colony Phase-I (Ext.) Shahrah Nazaria e Pakistan, Lahore 793-D, Block 'C' , Faisal Town, Lahore
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address: Ground Floor,6- Judicial Colony Phase-I (Ext.) Shahrah Nazaria e Pakistan, Lahore Address of Godown: NA Validity: 06.Feb.2024 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali ,Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali ,Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# DA/6-110/2016/3283 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, and Bangladesh. **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP (Section for Anticancer Tablet mentioned in previous GMP certificate)
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. 793-D, Block 'C' , Faisal Town, Lahore to register their products in Pakistan. Issued on 02-06-2020
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 32076 dated: 23-11-2021
	Details of fee submitted	PKR 50,000/- deposit Slip # 2037745 PKR 25,000/- deposit Slip # 1453143177
	The proposed proprietary name / brand name	Apalunix 60mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Apalutamide INN …….60 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-cancer Androgen receptor inhibitor indicated for the treatment of patients with • Metastatic castration-sensitive prostate. • Cancer. non-metastatic castration-resistant prostate cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Erleada (Janssen-Cilag Ltd. Belgium)
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Lianyungang Jari Pharmaceutical Co.Ltd No. 18 Zhenhua Road, Lianyungang, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months Batches: (20180101, 20180102, 20180103)

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against Erleada Tablet 60mg (Janssen-Cilag Ltd. Belgium) the reference product has been submitted. CDP has been performed against the same brand that is Erleada Tablet 60mg by Janssen-Cilag Ltd. in Acid media (pH 1.0-1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle (each contains 120 tablets)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months Batches:(3840002, 3840003, 3840004)

Evaluation by PEC:

S.No	Section	Shortcomings Communicated	Reply
1.	1.3.1.	Address mentioned in this section is different than address mentioned on Drug Sale Licence.	Revised new address in section 1.3.1 (Address on DSL after renewal changed)
2.	1.3.4	sole agency agreement / letter of authorization between applicant and marketing authorization holder have different address of applicant	Revised sole agency agreement/letter of authorization submitted. Firm has submitted copy of letter of authorization certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. Ground Floor,6-Judicial Colony Phase-I (Ext.) Shahrah Nazaria e Pakistan, Lahore 793-D, Block 'C' , Faisal Town, Lahore to register their products in Pakistan. Issued on : August 14, 2022
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by Drug Product manufacturer shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by Drug Product manufacturer
4.	3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of	Certificate of analysis by both drug substance manufacturer and drug product manufacturer are submitted.

		Analysis (CoA) of the same batch from Drug Substance/Active Pharmaceutical Ingredient manufacture.	
5.	3.2.P.5.2	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 30 minutes" in 0.25% (w/v) SLS in 0.05 M Sodium Phosphate Buffer, pH 4.5 whereas submitted specifications declare the dissolution limits as "NLT 75% in 60 minutes" in 2% SLS in Phosphate Buffer, pH 4.5 as dissolution medium. Justify the variation in time point of dissolution & dissolution medium..	Revised specifications with medium as Innovator product i.e 0.25% (w/v) SLS in 0.05 M Sodium Phosphate Buffer, pH 4.5 and dissolution time is 30 minutes are submitted**.**
Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. Registration letter will be issued upon submission of performance of dissolution testing as per revised specifications according to recommended by innovator drug product. **Firm shall submit full fee of Rs. 75,000/- for pre-approval change/correction in the address fo DSL as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**			

Agenda of Evaluator PEC-VI

Case No. 1: M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).

Central Licensing Board (CLB), in its 282nd meeting held on 321-08-2021, grant 03 addition sections (Capsule, oral dry powder suspension & Dry Powder Injection (Cephalosporin), vide letter no. 1-30/94-Lic(Vol-II), dated 20-09-2021.

1688.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Name, address of Manufacturing site.	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 21164 dated 27-07-2022	
	Details of fee submitted	**PKR 30,000/-**	**dated 30-04-2022(93609397821)**
	The proposed proprietary name / brand name	Roxime Injection 250mg IV/IM	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefuroxime Sodium eq. to Cefuroxime 250 mg	
	Pharmaceutical form of applied drug	Injection IV/IM	
	Pharmacotherapeutic Group of (API)	Antibiotic/ Cephalosporin	
	Reference to Finished product specifications	**USP Specifications**	
	Proposed Pack size	1X10ml	

	Proposed unit price	As per rule
	The status in reference regulatory authorities	**Zinacef 250 mg, IV/IM, MHRA, UK.**
	For generic drugs (me-too status)	Dowcef 250 mg IV/IM, Martin Dow.
	GMP status of the Finished product manufacturer	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512), GMP Certificate no. 89/2021-DRAP(AD-84281917-5101), dated 15-11-2021, based upon evaluation conducted on 13-08-2021, valid for 2 years. Capsule, oral dry powder suspension & Dry Powder Injection (Cephalosporin)
	Name and address of API manufacturer.	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: 16130701, 16130801,16130802. **Accelerated Time:** 16130701, 16130801,16130802.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Zinacef Injection 250 mg IV/IM (GSK Pakistan) (Batch no. 305 U) by performing quality tests (Identification, Assay, Constituted solution, water , pH., Sterilty and Bacterial endotoxin).
	Analytical method validation/verification of product	Method validation studies of UV spectrophotometer method have submitted including , ruggedness, LOD, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China
API Lot No.	

Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tri011-001	Tri011-002	Tri011-003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability studies.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

S.no.	Section	Description
1	**2.3.P.1**	Provide summarized information (including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug product.
2	**2.3.P.2.6**	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.
3	**2.3.R.1.1**	**Executed Production Documents** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
4	**3.2.S.4**	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.

		• COA of primary / secondary reference standard including source and lot number shall be provided.
5	**3.2.S.7**	• Significant change in accelerated stability studies of Drug substance manufacturer batch no 16130701, 16130801,16130802 (948 µg/mg to 868 µg/mg, 951 µg/mg to 878 µg/mg and 848 µg/mg to 880 µg/mg respectively). • Justification shall be submitted for not including Sterility and endotoxin testing in stability studies data
6	**3.2.P.3**	• Standard manufacturing procedure for Citi-Taxime 250 mg IM has been provided. Justification required. Furthermore, in Standard manufacturing procure preparation of solution, filtration and filling of liquid (1.00 to 1.20 ml) mentioned for Citi-Taxime. Justification shall be submitted. • The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.
7	**3.2.P.5**	• In Method validation protocol no. QC/CEPH/MVD/007, issue date 20-11-2021, Testing procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC. • Method validation report for Roxime 250 mg injection (SAP/P/260), procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC. • Detailed analytical procedures used for testing the drug product shall be provided.
8	**3.2.P.7**	Please provide detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided. Please also provide USP type of glass vials.
9	**3.2.P.8**	• Stability study record of real time batch no. TRI009-003 shall be provided. • In 3.2. P.5. Method validation protocol and report is provided of UV spectrophotometer method. However, in stability studies HPLC chromatograms are provided, which are not in accordance with USP official monograph. As in USP monograph Orcinol in water containing 1.5 mg per mL has been used as internal standard and the resolution, *R*, between the analyte and internal standard peaks is not less than 3.5. However, in provided chromatograms there is no peak of Orcinol. Justification required. • Documents for the procurement of API with approval from DRAP shall be provided. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Please provide Certificate of analysis of API which is actually used in manufacturing of product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

1689.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).
	Name, address of Manufacturing site.	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21165 dated 27-07-2022
	Details of fee submitted	**PKR 30,000/-** **dated 30-04-2022(57293016)**
	The proposed proprietary name / brand name	Roxime Injection 750mg IV/IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefuroxime Sodium eq. to Cefuroxime 750 mg
	Pharmaceutical form of applied drug	Injection IV/IM
	Pharmacotherapeutic Group of (API)	Antibiotic/ Cephalosporin
	Reference to Finished product specifications	**USP Specifications**
	Proposed Pack size	1X10ml
	Proposed unit price	As per rule
	The status in reference regulatory authorities	**Zinacef 750 mg, IV/IM, MHRA, UK.**
	For generic drugs (me-too status)	Dowcef 750 mg IV/IM, Martin Dow.
	GMP status of the Finished product manufacturer	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512), GMP Certificate no. 89/2021-DRAP(AD-84281917-5101), dated 15-11-2021, based upon evaluation conducted on 13-08-2021, valid for 2 years. Capsule, oral dry powder suspension & Dry Powder Injection (Cephalosporin)
	Name and address of API manufacturer.	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: 16130701, 16130801,16130802. **Accelerated Time:** 16130701, 16130801,16130802.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications,

		analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Zinacef Injection 750 mg IV/IM (GSK Pakistan) by performing quality tests (Identification, Assay, Constituted solution, water , pH., Sterility and Bacterial endotoxin).
	Analytical method validation/verification of product	Method validation studies of UV spectrophotometer method have submitted including , ruggedness, LOD, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tri010-001	Tri010-002	Tri010-003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability studies.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

S.no.	Section	Description
1	2.3.P.1	Provide summarized information (including type of diluent, its composition, quantity or specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent to be provided along with the applied drug product.
2	2.3.P.2.6	Compatibility studies for the dry powder for injections and dry powder for suspension performed as per the instructions provided in individual label of the drug product.
3	2.3.R.1.1	**Executed Production Documents** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product fo stability studies data is provided in Module 3 section 3.2.P.8.3
4	3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability precision) performed by the Drug Product manufacturer for both compendial as well compendial drug substance(s) shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug manufacturer used during product development and stability studies, along with Certi Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical In manufacture. • COA of primary / secondary reference standard including source and lot number shall be p
5	3.2.S.7	• Significant change in accelerated stability studies of Drug substance manufacturer b 16130701, 16130801,16130802 (948 µg/mg to 868 µg/mg, 951 µg/mg to 878 µg/mg and 84 to 880 µg/mg respectively). • Justification shall be submitted for not including Sterility and endotoxin testing in stabilit data
6	3.2.P.3	• Standard manufacturing procedure for Citi-Taxime 250 mg IM has been provided. Just required. Furthermore, in Standard manufacturing procure preparation of solution, filtra filling of liquid (1.00 to 1.20 ml) mentioned for Citi-Taxime. Justification shall be submitt • The process validation protocols do not contain any steps to ensure the sterilization of v rubber stopper is adequately performed, further the time and temperature of sterilization also not validated. Justification is required in this regard.
7	3.2.P.5	• In Method validation protocol no. QC/CEPH/MVD/007, issue date 20-11-2021, Testing p use is UV spectrophotometer at wavelength of 245nm. However, In official monograph method on HPLC. • Method validation report for Roxime 250 mg injection (SAP/P/260), procedure use spectrophotometer at wavelength of 245nm. However, In official monograph USP its me HPLC. • Detailed analytical procedures used for testing the drug product shall be provided.
8	3.2.P.7	Please provide detail of the container closure systems, description of the primary container systems, including materials of construction, unit count or fill size, container size or volume provided. Please also provide USP type of glass vials.
9	3.2.P.8	• Stability study record of real time batch no. TRI009-003 shall be provided. • In 3.2. P.5. Method validation protocol and report is provided of UV spectrophotometer However, in stability studies HPLC chromatograms are provided, which are not in accorda USP official monograph. As in USP monograph Orcinol in water containing 1.5 mg per been used as internal standard and the resolution, *R*, between the analyte and internal standa is not less than 3.5. However, in provided chromatograms there is no peak of Orcinol. Just required. • Documents for the procurement of API with approval from DRAP shall be provided. • Record of Digital data logger for temperature and humidity monitoring of stability chamb time and accelerated) shall be submitted. • Please provide Certificate of analysis of API which is actually used in manufacturing of p • Submit compliance record of HPLC software 21CFR & audit trail reports on product te each analysis performed during the study. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned re authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import).

		• Summary of additional stability studies (if applicable) e.g. in-use studies for drug produc are to be reconstituted before use, along with proposed in-use storage statement and in-u life shall be provided.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

1690.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Name, address of Manufacturing site.	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512).	
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)	
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)	
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales	
	Dy. No. and date of submission	Dy. No. 21166 dated 27-07-2022	
	Details of fee submitted	**PKR 30,000/-**	**dated 30-04-2022(72888767)**
	The proposed proprietary name / brand name	Roxime Injection 1.5 g IV/IM	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Cefuroxime Sodium eq. to Cefuroxime 1.5 g	
	Pharmaceutical form of applied drug	vial IV/IM	
	Pharmacotherapeutic Group of (API)	Antibiotic/ Cephalosporin	
	Reference to Finished product specifications	**USP Specifications**	
	Proposed Pack size	1X10ml	
	Proposed unit price	As per rule	
	The status in reference regulatory authorities	**Zinacef 1.5 g, IV/IM, MHRA, UK.**	
	For generic drugs (me-too status)	Dowcef 1.5g IV/IM, Martin Dow.	
	GMP status of the Finished product manufacturer	M/s Citi Pharma(Pvt.) Ltd. 3- Km, Head Balloki Road, Phool Nagar, Kasur. (DML No. 000512), GMP Certificate no. 89/2021-DRAP(AD-84281917-5101), dated 15-11-2021, based upon evaluation conducted on 13-08-2021, valid for 2 years. Capsule, oral dry powder suspension & Dry Powder Injection (Cephalosporin)	
	Name and address of API manufacturer.	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.	

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: **Real Time**: 16130701, 16130801,16130802. **Accelerated Time:** 16130701, 16130801,16130802.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Zinacef Injection 1.5g IV/IM (GSK Pakistan) by performing quality tests (Identification, Assay, Constituted solution, water , pH., Sterility and Bacterial endotoxin).
	Analytical method validation/verification of product	Method validation studies of UV spectrophotometer method have submitted including , ruggedness, LOD, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Shandong Luoxin Phamaceutical Group Hengxin Pharmaceutical Co, Ltd. West side of Yanbin Road, Economic Development zone, feixian, Linyi, Shandong, P.R. China		
API Lot No.			
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Tri009-001	Tri009-002	Tri009-003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No previous inspection of the firm has been conducted for verification of stability studies.

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

Remarks of Evaluator:

S.no.	Section	Description
1	**1.5.4**	Justification shall be provided for pack size of 1.5 g IM/IV injection (10 ml). However, as per innovator its dilution is required with 15 ml water for injection.
2	**2.3.P.1**	Provide summarized information (including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug product.
3	**2.3.P.2.6**	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.
4	**2.3.R.1.1**	**Executed Production Documents** Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
5	**3.2.S.4**	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted. • Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. • COA of primary / secondary reference standard including source and lot number shall be provided.
6	**3.2.S.7**	• Significant change in accelerated stability studies of Drug substance manufacturer batch no 16130701, 16130801,16130802 (948 µg/mg to 868 µg/mg, 951 µg/mg to 878 µg/mg and 848 µg/mg to 880 µg/mg respectively). • Justification shall be submitted for not including Sterility and endotoxin testing in stability studies data
7	**3.2.P.3**	• Standard manufacturing procedure for Citi-Taxime 250 mg IM has been provided. Justification required. Furthermore, in Standard manufacturing procure preparation of solution, filtration and filling of liquid (1.00 to 1.20 ml) mentioned for Citi-Taxime. Justification shall be submitted. • The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.
8	**3.2.P.5**	• In Method validation protocol no. QC/CEPH/MVD/007, issue date 20-11-2021, Testing procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC. • Method validation report for Roxime 250 mg injection (SAP/P/260), procedure use is UV spectrophotometer at wavelength of 245nm. However, In official monograph USP its method on HPLC.

		• Detailed analytical procedures used for testing the drug product shall be provided.
9	**3.2.P.7**	Please provide detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided. Please also provide USP type of glass vials.
10	**3.2.P.8**	• Stability study record of real time batch no. TRI009-003 shall be provided. • In 3.2. P.5. Method validation protocol and report is provided of UV spectrophotometer method. However, in stability studies HPLC chromatograms are provided, which are not in accordance with USP official monograph. As in USP monograph Orcinol in water containing 1.5 mg per mL has been used as internal standard and the resolution, *R*, between the analyte and internal standard peaks is not less than 3.5. However, in provided chromatograms there is no peak of Orcinol. Justification required. • Documents for the procurement of API with approval from DRAP shall be provided. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Please provide Certificate of analysis of API which is actually used in manufacturing of product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import). • Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

Case No.02 Registration applications of local manufacturing of human drugs submitted on Form 5F (New Section)

The central licensing Board in its 282nd meeting held on 31-08-2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five sections in the name of M/s Fleming Pharmaceutical, 23- Km Lahore- Sheikhupura Road, Lahore.

i. Oral Dry powder suspension (Penicillin)
ii. Capsule (Penicillin)
iii. Tablet (Penicillin)
iv. Dry Powder injectable(Penicillin)
v. Dry powder injectable (Carbapenem)

1691.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical 23- Km Lahore-Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23967 dated 24/08/2022
	Details of fee submitted	PKR 30,000/-: dated 12/08/2022(39263912)

	The proposed proprietary name / brand name	**Dori-F Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Doripenem Monohydrate eq. to Anhydrous Doripenem 500 mg.
	Pharmaceutical form of applied drug	Injectable Vial
	Pharmacotherapeutic Group of (API)	Carbapenems (Beta-Lactam Antibiotic)
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Doripenem Hydrate M/s Shionogi Inc, PMDA Approved.
	For generic drugs (me-too status)	Ronim Injection by M/s Genix Pharma, Reg. No. 088904
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Dry Powder injectable (Carbapenem)
	Name and address of API manufacturer.	KOPRAN Research Laboratories. Ltd K-4/4, Additonal MIDC, Post Birwadi Tal, Mahad, Dist. Raigad 402302, Maharashtra State India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm is submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (DPIV-P1807007, DPIV-P1807008, DPIV-P1807009)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader Ronim Injection 500 mg by Genix Pharma by performing quality tests (Identification, Assay, etc.).

	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	KOPRAN Research Laboratories. Ltd K-4/4, Additional MIDC, Post Birwadi Tal, Mahad, Dist. Raigad 402302, Maharashtra State India.		
API Lot No.	DPIV-P2108007		
Description of Pack (Container closure system)	Dori-F injection is filled in Glass vial further packed in unit carton along with patient leaflet insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	400 Vial	400 Vial	400 Vial
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	06-03-2022	06-03-2022	06-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML granted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. WHO-GMP/CERT/KD/89275/2020/11/33788 issued by F&DA valid till 19-10-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Documents for the procurement of API with approval from DRAP, Lahore is provided, specifying the import of 1 kg of Doripenem Monohydrate vide DRAP clearance no. 831/2022DRAP, dated 18-01-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of evaluator:

S.no.	Section	Remarks of evaluator	Response of Firm
1.	**1.5.6**	Justify the finished product specifications as "In-house specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Specification has been revised to "Japanese Pharmacopoeia". Fee for change in spec has been submitted. **Dori-F 250mg INJECTION**: *SLIP NUMBER: 359794707110* **DORI-F 500mg INJECTION:** *SLIP NUMBER: 8284978682*

<table>
<tr>
<td>2</td>
<td>3.2.S.4</td>
<td>

Justify the use of drug substance having in house specifications while the drug substance specifications are present in JP monograph for “Doripenem hydrate”
Justify the limit of water from 4.0 – 6% in drug substance specifications, while JP monograph specifies the limit from 4.0 – 5.0%.
Justify the limit of Optical rotation from +30° to +40° in drug substance specifications, while JP monograph specifies the limit from +33° to +38°.
Justify why the test for residue on ignition is not performed for the drug substance since it is recommended in JP monograph.
Justify the use of a different analytical method for assay testing of drug substance from that specified in JP monograph. The method of drug substance manufacturer is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay

</td>
<td>

Specification has been revised to “Japanese Pharmacopoeia” and the same will be used for commercial batches.
Comparison of JP & Manufacturer Specs is tabulated below:

<table>
<tr><th>Parameter</th><th>JP Specs.</th><th>Mfg. Specs.</th><th>Fleming Results</th></tr>
<tr><td>Identification</td><td>By UV
By IR</td><td>By HPLC
By IR</td><td>Complies</td></tr>
<tr><td>Water</td><td>4.0 – 5.0%</td><td>4.0 – 5.5%</td><td>4.2</td></tr>
<tr><td>pH</td><td>4.5 and 6.0</td><td>4.0 – 6.0</td><td>4.92</td></tr>
<tr><td>Optical rotation</td><td>+33 - + 38°</td><td>+30 - + 40°</td><td>+35.2</td></tr>
<tr><td>Residue on ignition</td><td>Not more than 0.1%</td><td>Not required to be perform</td><td>Not performed</td></tr>
<tr><td>Sulphated Ash</td><td>Not required to be perform</td><td>NMT 0.2%</td><td>0.088%</td></tr>
<tr><td>Assay</td><td>97 – 102% OAB</td><td>98 – 102% OAB</td><td>98.80%</td></tr>
</table>

It is requested to accept the revised limit for the test for “Water” as per JP monograph. Already stated results are within pharamcopoeial limits. COA is attached.
It is requested to accept the revised limit for the test for “Optical rotation” as per JP monograph. Our already stated results are within pharamcopoeial limits. COA is attached.
HPLC based method was used and the same was validated for following parameters:
<ol type="1.1.">
System suitability.
<ol type="a.">
RSD.
Tailing factor.
Theoretical plates.

Specificity
Linearity
Accuracy
Repeatability
Intermediate Precision
Stability of Solution
Robustness

Since Specs has been revised to JP monograph so the same will be used for commercial batches.
</td>
</tr>
<tr>
<td>3</td>
<td>3.2.S.7</td>
<td>24 months Real time stability data has been provide for drug substance. However as per COA it has 3 years shelf life. Please provide complete stability data</td>
<td>Not submitted</td>
</tr>
</table>

<table>
<tr><td>4</td><td>3.2.P.1</td><td>• Justify how 526mg of Doripenem Monohydrate eq.to Doripenem is equivalent to 500mg of Doripenem as per the label claim.
• Justify how 263mg of Doripenem Monohydrate eq.to Doripenem is equivalent to 250mg of Doripenem as per the label claim.</td><td>Filled weight per vial was calculated based on Factor and potency of API used.

As per JP monograph:
Molecular weight of Doripenem Monohydrate : 438.50 g/mol
Molecular weight of Doripenem : 420.5 g/mol
Factor : 1.04
Potency of API used = 98.80 % on anhydrous bases</td></tr>
<tr><td>5</td><td>3.2.P.2</td><td>Please provide complete details of product against which Pharmaceutical Equivalence has been performed.
Justification shall be submitted for not performing sterility, endotoxin testing etc. in Pharmaceutical equivalence studies.</td><td>Pharmaceutical Equivalence was performed against a competitor Product

Competitor Name: Genix Pharmaceuticals (Pvt.) Limited
Brand Name : Ronim Injection
However, Firm has not provided the details of batch no etc. used details

1.3 Reference product information
<table><tr><th>Sr #</th><th>Parameters</th><th>Acceptable limits /Information</th><th>Actual Results</th></tr><tr><td>1</td><td>Description</td><td>--</td><td>White to Sligthtly yellowish, off white crystalline powder filled in glass glass vial and properly sealed, labeled and packed in white colored printed unit card board box.</td></tr><tr><td>2</td><td>Batch No.</td><td>--</td><td>012I050</td></tr><tr><td>3</td><td>Average weight</td><td>--</td><td>Avg. 532.8mg</td></tr><tr><td>4</td><td>Manufacturing date</td><td>--</td><td>15-09-21</td></tr><tr><td>5</td><td>Expiry date</td><td>--</td><td>14-09-23</td></tr><tr><td>6</td><td>Manufacturer</td><td>--</td><td>Genix pharma (Pvt.) Ltd. Pharmaceuticals.</td></tr><tr><td>7</td><td>pH</td><td>--</td><td>5.1</td></tr><tr><td>8</td><td>Water content</td><td>--</td><td>4.13%</td></tr><tr><td>10</td><td>Assay</td><td>--</td><td>98.24%</td></tr></table>
Microbial tests are generally related to manufacturing process, Microbes are not uniformity distributed in a whole batch, a portion of batch may have different results as compared to other if environmental conditions are changed during manufacturing. So sterility test and BET was not performed with Competitor Pack, however We performed both tests for our trials.
However, we assure the competent authority to perform both tests i.e sterility & endotoxin testing if directed.</td></tr>
<tr><td>6</td><td>3.2.P.3</td><td>The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.</td><td>Details of steps is mentioned in BMRs, Process validation protocol has been revised and accordingly. We assure the competent authority that Validation of manufacturing process will be carried out on commercial batches.
The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper</td></tr>
<tr><td>7</td><td>3.2.P.5</td><td>• Justify the drug product specifications section</td><td>Our trial results are within limits as per JP monograph:
Dori-F 250mg Injection:</td></tr>
</table>

(3.2.P.5.1) with **water** contents from 4.0% to 5.5% while the JP monograph for the drug product specifies water contents to be 4.0 to 5.0%.

- Justify the drug product specifications section (3.2.P.5.1) with **pH** from 4-6 while the JP monograph for the drug product specifies pH to be 4.5-6.0.
- Justify the **limit of assay** from 90 – 110% since the JP monograph specifies the assay limit from 95 – 105%.
- Justify the use of a **different analytical method** for assay testing of drug product from that specified in JP monograph. The analytical method of drug product is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, total run time and retention time, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.

Parameter	**JP Specs.**	**Results T-001**	**Results T-002**	**Results T-003**
Water	4.0 – 5.0%	4.7	4.4	5.0
pH	4.5 and 6.0	5.01	4.98	4.52
Assay	95 – 105%	99.82%	99.70%	99.52

a. It is requested to accept the revised limit for the test for "Water" as per JP monograph. We assure to use JP Specs. COA is submitted

b. It is requested to accept the revised limit for the test for "pH" as per JP monograph. Our already stated results are within pharamcopoeial limits. COA is submitted.

c. It is requested to accept the revised limit for the test for "Assay" as per JP monograph. Our already stated results are within pharamcopoeial limits. COA is submitted.

d. Comparison of JP method and Fleming method is tabulated below:

HPLC MFG. METHOD	**HPLC METHOD BY JP**
• **Mobile phase:** Buffer & Acetonitrile:: 96: 4 • **Chromatographic Conditions:** **Column** : 4.6 mm x 250 mm, 5µm ODS RP-8 **Detector** : 295 nm **Column Temperature** :40 ^{0}C **Injection volume** : 10 µl **Flow rate** : 1ml/min	• **Mobile phase:** Buffer & Acetonitrile :: 97: 3 • **Chromatographic Conditions:** **Column** : 4.6 mm x 150 mm, 5µm ODS RP-8 **Detector** : 300 nm **Column Temperature** : 25^{0}C **Injection volume** : 10 µl **Flow rate** : Adjust so that the retention time should be 15 minutes.

We used different HPLC based method however the same was validated for following parameters:

1.2. System suitability.
   a. RSD.
   b. Tailing factor.
   c. Theoretical plates.
1.2. Specificity
1.3. Linearity

			1.4. Accuracy 1.5. Repeatability 1.6. Intermediate Precision 1.7. Stability of Solution 1.8. Robustness Moreover, we have tested our product Dori-F Injection 500 mg (T-001) at 8th Month Stability study as per JP monograph as well as on manufacturer method. Comparison is tabulated below: **Parameter** / **JP Method** / **Mfg. Method** Weight of Ref Standard Taken: 25 mg Conc.(0.125mg/mL) / 50mg Conc.(0.1mg/mL) Average Peak Area: 5242.63 / 4058.01 % RSD: 0.44% / 0.13% Retention Time: 15 minutes / 8 minutes Tailing Factor: 1.23 / 1.01 Assay Results: 100.31% / 99.21% **NO data is submitted**
8	**3.2.P.5.4**	• The copies of complete analysis of at least two batches shall be provided.	Submitted.
9	**3.2.P.7**	• Please provide detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided. Please also provide USP type of glass vials. • In BMR it is mentioned that USP Type –III glass is used. Whereas in section 3.2.P.1 it is mentioned USP TYPE-II glass vials. Justification required.	• Detail of the container closure systems is provided below: ➢ Transparent Glass vial ➢ Volume 10ml ➢ USP Type-II ➢ Rubber Stopper 20 mm ➢ Flip of seal 20 mm We request to ignore the typographic error, USP Type –II glass vial was used for Trial batches.
10	**3.2.P.8**	a. In stability studies acceptance criteria, limits of tests i.e. **pH , water , assay** etc. are not in accordance with Pharmacopoeia. b. **Sterility testing, Bacterial endotoxin testing, Foreign Insoluble matter** has not been performed in stability studies. c. Documents for the procurement of API with	a. Specification has been revised as per JP monograph, So it is requested to accept our current stability data for the test for "pH, water, assay". Furthered, our already submitted results are within pharamcopoeial limits. We assure to use JP spec for commercial batches. b. In stability studies Sterility testing, Bacterial endotoxin testing, Foreign Insoluble matter has been performed. ***Revised Stability summary provided.*** c. Documents for the procurement of API with approval from DRAP, Lahore is provided, specifying the import of 1 kg of

		approval from DRAP shall be provided. d. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. e. Please provide Certificate of analysis of API which is actually used in manufacturing of product. f. Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Doripenem Monohydrate vide DRAP clearance no. 831/2022DRAP, dated 18-01-2022 d. Record of Digital data logger submitted. e. Certificate of analysis of API(DPIV-P2108007) is provided. f. Compliance record of HPLC software 21CFR & audit trail reports is submitted.

Decision Approved with Japanese Pharmacopoeia(JP) specifications.

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

Registration letter will be issued upon submission of fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 along with following data:

- **Performance of analysis of next time point of long term stability studies of drug product as well as analytical method verification report of Drug substance and Drug product as per JP monograph.**
- **Performance of residue on ignition test of drug substance as per Japanese Pharmacopoeia(JP) by M/s Fleming Pharmaceutical.**
- **Complete stability data of drug substance as per claimed shelf life (03 years) by the drug substance manufacturer.**

1692.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1739 dated 24/08/2022
	Details of fee submitted	PKR 30,000/-: dated 12/08/2022
	The proposed proprietary name / brand name	Dori-F Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Doripenem Monohydrate eq. to Anhydrous Doripenem 250 mg.
	Pharmaceutical form of applied drug	Type-II Glass Vial
	Pharmacotherapeutic Group of (API)	Carbapenems (Beta-Lactam Antibiotic)

	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Doripenem Hydrate M/s Shionogi Inc, PMDA Approved.
	For generic drugs (me-too status)	Ronim Injection by M/s Genix Pharma, Reg. No. 093113
	GMP status of the Finished product manufacturer	New license granted on 14/09/2021 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	KOPRAN Research Laboratories. Ltd K-4/4, Additonal MIDC, Post Birwadi Tal, Mahad, Dist. Raigad 402302, Maharashtra State India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm is submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DPIV-P1807007, DPIV-P1807008, DPIV-P1807009)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader Ronim Injection 250 mg by Genix Pharma by performing quality tests (Identification, Assay, etc.).
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	KOPRAN Research Laboratories. Ltd K-4/4, Additional MIDC, Post Birwadi Tal, Mahad, Dist. Raigad 402302, Maharashtra State India.
API Lot No.	DPIV-P2008015
Description of Pack (Container closure system)	Dori-F injection is filled in Glass vial further packed in unit carton along with patientleaflet insert
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	400 Vial	400 Vial	400 Vial
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	06-03-2022	06-03-2022	06-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML granted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. WHO-GMP/CERT/KD/89275/2020/3118/11 issued by F&DA valid till 22/10/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Documents for the procurement of API with approval from DRAP, Lahore is provided, specifying the import of 1 kg of Doripenem Monohydrate vide DRAP clearance no. 831/2022DRAP, dated 18-01-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Section	Remarks of evaluator	Response of Firm
1.	**1.5.6**	Justify the finished product specifications as "Inhouse specifications" since the drug product monograph is available in Japanese Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Specification has been revised to "Japanese Pharmacopoeia". Fee for change in spec has been submitted. **Dori-F 250mg INJECTION**: *SLIP NUMBER: 359794707110* **DORI-F 500mg INJECTION:** *SLIP NUMBER: 8284978682*
2	3.2.S.4	• Justify the use of drug substance having in house specifications while the drug substance specifications are present in JP monograph for "Doripenem hydrate" • Justify the limit of water from 4.0 – 6% in drug substance specifications, while JP monograph specifies the limit from 4.0 – 5.0%. • Justify the limit of Optical rotation from +30° to +40° in drug substance specifications,	• Specification has been revised to "Japanese Pharmacopoeia" and the same will be used for commercial batches. Comparison of JP & Manufacturer Specs is tabulated below:

Parameter	JP Specs.	Mfg. Specs.	Fleming Results
Identification	By UV By IR	By HPLC By IR	Complies
Water	4.0 – 5.0%	4.0 – 5.5%	4.2

		while JP monograph specifies the limit from +33º to +38º. • Justify why the test for residue on ignition is not performed for the drug substance since it is recommended in JP monograph. • Justify the use of a different analytical method for assay testing of drug substance from that specified in JP monograph. The method of drug substance manufacturer is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay	<table><tr><td>pH</td><td>4.5 and 6.0</td><td>4.0 – 6.0</td><td>4.92</td></tr><tr><td>Optical rotation</td><td>+33 - + 38º</td><td>+30 - + 40º</td><td>+35.2</td></tr><tr><td>Residue on ignition</td><td>Not more than 0.1%</td><td>Not required to be perform</td><td>Not performed</td></tr><tr><td>Sulphated Ash</td><td>Not required to be perform</td><td>NMT 0.2%</td><td>0.088%</td></tr><tr><td>Assay</td><td>97 – 102% OAB</td><td>98 – 102% OAB</td><td>98.80%</td></tr></table> • It is requested to accept the revised limit for the test for "Water" as per JP monograph. Already stated results are within pharamcopoeial limits. **COA is attached**. • It is requested to accept the revised limit for the test for "Optical rotation" as per JP monograph. Our already stated results are within pharamcopoeial limits. **COA is attached**. • HPLC based method was used and the same was validated for following parameters: 1.3. **System suitability.** a. RSD. b. Tailing factor. c. Theoretical plates. 1.2. **Specificity** 1.3. **Linearity** 1.4. **Accuracy** 1.5. **Repeatability** 1.6. **Intermediate Precision** 1.**7. Stability of Solution** 1.8. **Robustness** Since Specs has been revised to **JP monograph** so the same will be used for commercial batches.
3	3.2.S.7	24 months Real time stability data has been provide for drug substance. However as per COA it has 3 years shelf life. Please provide complete stability data	Not submitted
4	**3.2.P.1**	• Justify how 526mg of Doripenem Monohydrate eq.to Doripenem is equivalent to 500mg of Doripenem as per the label claim. • Justify how 263mg of Doripenem Monohydrate eq.to Doripenem is equivalent to 250mg of Doripenem as per the label claim.	Filled weight per vial was calculated based on Factor and potency of API used. As per JP monograph: Molecular weight of Doripenem Monohydrate : 438.50 g/mol Molecular weight of Doripenem : 420.5 g/mol **Factor** : 1.04 **Potency of API used** = 98.80 % on anhydrous bases

5	3.2.P.2	Please provide complete details of product against which Pharmaceutical Equivalence has been performed. Justification shall be submitted for not performing sterility, endotoxin testing etc. in Pharmaceutical equivalence studies.	Pharmaceutical Equivalence was performed against a competitor Product **Competitor Name**: Genix Pharmaceuticals (Pvt.) Limited **Brand Name** : Ronim Injection ***However, Firm has not provided the details of batch no etc. used details***

1.3 Reference product information

Sr #	Parameters	Acceptable limits /Information	Actual Results
1	Description	--	White to Sligthtly yellowish, off white crystalline powder filled in glass glass vial and properly sealed, labeled and packed in white colored printed unit card board box.
2	Batch No.	--	0121050
3	Average weight	--	Avg. 532.8mg
4	Manufacturing date	--	15-09-21
5	Expiry date	--	14-09-23
6	Manufacturer	--	Genix pharma (Pvt.) Ltd. Pharmaceuticals.
7	pH	--	5.1
8	Water content	--	4.13%
10	Assay	--	98.24%

Microbial tests are generally related to manufacturing process, Microbes are not uniformity distributed in a whole batch, a portion of batch may have different results as compared to other if environmental conditions are changed during manufacturing. So sterility test and BET was not performed with Competitor Pack, however We performed both tests for our trials.
However, we assure the competent authority to perform both tests i.e sterility & endotoxin testing if directed.

6	3.2.P.3	The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper is adequately performed, further the time and temperature of sterilization cycle is also not validated. Justification is required in this regard.	Details of steps is mentioned in BMRs, Process validation protocol has been revised and accordingly. We assure the competent authority that Validation of manufacturing process will be carried out on commercial batches. **The process validation protocols do not contain any steps to ensure the sterilization of vials and rubber stopper**
7	3.2.P.5	• Justify the drug product specifications section (3.2.P.5.1) with **water** contents from 4.0% to 5.5% while the JP monograph for the drug product specifies water contents to be 4.0 to 5.0%. • Justify the drug product specifications section (3.2.P.5.1) with **pH** from 4-6 while the JP monograph for the drug product specifies pH to be 4.5-6.0.	Our trial results are within limits as per JP monograph: Dori-F 250mg Injection:

Parameter	**JP Specs.**	**Results T-001**	**Results T-002**	**Results T-003**
Water	4.0 – 5.0%	4.7	4.4	5.0
pH	4.5 and 6.0	5.01	4.98	4.52
Assay	95 – 105%	99.82%	99.70%	99.52

- Justify the **limit of assay** from 90 – 110% since the JP monograph specifies the assay limit from 95 – 105%.
- Justify the use of a **different analytical method** for assay testing of drug product from that specified in JP monograph. The analytical method of drug product is different in terms of HPLC column specifications, column temperature, mobile phase, UV detector wavelength, flow rate, total run time and retention time, standard preparation method and final concentration of standard solution, sample preparation method and final concentration of sample solution, system suitability requirements and acceptance criteria and the formula for calculation of results of assay.

e. It is requested to accept the revised limit for the test for "Water" as per JP monograph. We assure to use JP Specs. COA is submitted

f. It is requested to accept the revised limit for the test for "pH" as per JP monograph. Our already stated results are within pharamcopoeial limits. COA is submitted.

g. It is requested to accept the revised limit for the test for "Assay" as per JP monograph. Our already stated results are within pharamcopoeial limits. COA is submitted.

h. Comparison of JP method and Fleming method is tabulated below:

HPLC MFG. METHOD	HPLC METHOD BY JP
• **Mobile phase:** Buffer & Acetonitrile:: 96: 4 • **Chromatographic Conditions:** **Column** : 4.6 mm x 250 mm, 5µm ODS RP-8 **Detector** : 295 nm **Column Temperature** :40 ^{0}C **Injection volume** : 10 µl **Flow rate** : 1ml/min	• **Mobile phase:** Buffer & Acetonitrile :: 97: 3 • **Chromatographic Conditions:** **Column** : 4.6 mm x 150 mm, 5µm ODS RP-8 **Detector** : 300 nm **Column Temperature** : 25^{0}C **Injection volume** : 10 µl **Flow rate** : Adjust so that the retention time should be 15 minutes.

We used different HPLC based method however the same was validated for following parameters:

1.4. System suitability.
   a. RSD.
   b. Tailing factor.
   c. Theoretical plates.
1.2. Specificity
1.3. Linearity
1.4. Accuracy
1.5. Repeatability
1.6. Intermediate Precision
1.7. Stability of Solution
1.8. Robustness

Moreover, we have tested our product Dori-F Injection 500 mg (T-001) at 8th Month Stability study as per JP monograph as well as on manufacturer method. Comparison is tabulated below:

Parameter	JP Method	Mfg. Method
Weight of Ref Standard Taken	25 mg Conc.(0.125mg/mL)	50mg Conc.(0.1mg/mL)
Average Peak Area	5242.63	4058.01
% RSD	0.44%	0.13%
Retention Time	15 minutes	8 minutes
Tailing Factor	1.23	1.01
Assay Results	100.31%	99.21%
NO data is submitted		

8	**3.2.P.5.4**	• The copies of complete analysis of at least two batches shall be provided.	Submitted.
9	**3.2.P.7**	• Please provide detail of the container closure systems, description of the primary container closure systems, including materials of construction, unit count or fill size, container size or volume shall be provided. Please also provide USP type of glass vials. • In BMR it is mentioned that USP Type –III glass is used. Whereas in section 3.2.P.1 it is mentioned USP TYPE-II glass vials. Justification required.	• Detail of the container closure systems is provided below: ➢ Transparent Glass vial ➢ Volume 10ml ➢ USP Type-II ➢ Rubber Stopper 20 mm ➢ Flip of seal 20 mm We request to ignore the typographic error, USP Type –II glass vial was used for Trial batches.
10	**3.2.P.8**	g. In stability studies acceptance criteria, limits of tests i.e. **pH , water , assay** etc. are not in accordance with Pharmacopoeia. h. **Sterility testing, Bacterial endotoxin testing, Foreign Insoluble matter** has not been performed in stability studies. i. Documents for the procurement of API with approval from DRAP shall be provided. j. Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. k. Please provide Certificate of analysis of API which is actually used in manufacturing of product.	a. Specification has been revised as per JP monograph, So it is requested to accept our current stability data for the test for "pH, water, assay". Furthered, our already submitted results are within pharamcopoeial limits. We assure to use JP spec for commercial batches. b. In stability studies Sterility testing, Bacterial endotoxin testing, Foreign Insoluble matter has been performed. ***Revised Stability summary provided.*** c. Documents for the procurement of API with approval from DRAP, Lahore is provided, specifying the import of 1 kg of Doripenem Monohydrate vide DRAP clearance no. 831/2022DRAP, dated 18-01-2022 d. Record of Digital data logger is submitted. e. Certificate of analysis of API(DPIV-P2108007) is provided. f. Compliance record of HPLC software 21CFR & audit trail reports is submitted.

	l. Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	

Decision Approved with Japanese Pharmacopoeia(JP) specifications.

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

Registration letter will be issued upon submission of fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021 along with following data:

- **Performance of analysis of next time point of long term stability studies of drug product as well as analytical method verification report of Drug substance and Drug product as per JP monograph.**
- **Performance of residue on ignition test of drug substance as per Japanese Pharmacopoeia(JP) by M/s Fleming Pharmaceutical.**
- **Complete stability data of drug substance as per claimed shelf life (03 years) by the drug substance manufacturer.**

Case no. 3. Registration applications of local manufacturing of human drugs submitted on Form 5F format (Deferred cases)

1693.	Name, address of Applicant / Marketing Authorization Holder	M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot # 22-23, Industrial triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Standpharm Pakistan:** Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML. **M/s Vision Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	Evidence of approval of manufacturing facility	**M/s Vision Pharmaceuticals:** The firm has provided sterile Dry powder injection vials (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11788: 20-04-2021
	Details of fee submitted	PKR 50,000/-: 09-03-2021
	The proposed proprietary name / brand name	CISEC 40mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole sodium eq. to Omeprazole (as lyophilized powder) …….40mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications

	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion of M/s Sandoz Novartis (MHRA approved)
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma Pakistan
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and comparator product Risek Injection 40mg (B # 789P06) of M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of drug substance.

		Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
API Lot No.	1702901 1702902 1702903
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Rapid 40mg I.V Injection

Batch No.	1803707	1803708	1803709
Batch Size	10,000 vials	10,000 vials	10,000 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has procured material from their semi basic manufacturing facility.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail on testing reports of product.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Sr. No.	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report from M/s Vision Pharmaceuticals Pvt, Ltd. Islamabad.

2.	Certificate of analysis of both drug substance manufacturer and drug product manufacturer are required.	The firm has submitted COAs of 3 batches of omeprazole lyophilized powder. The firm stated that we have a combined QC of both Formulation (000517) and Semi-Basic (000806) facility having same equipment and analysts for both facilities.
3.	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and Risek 40mg Injection (B # 789P06) manufactured by M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
4.	Scientific justification is required for performing assay testing by UV method instead of HPLC method.	As the stability studies of the Bulk lyophilized material is performed by the Bulk manufacturer in the same QC lab with the same instrument (on HPLC) so just for verification purpose we performed the stability of the said product by UV. The firm has not submitted stability study data performed by HPLC alongwith raw data sheets, chromatograms and summary data sheets.
5.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing record of 3 batches for which stability studies were carried out.
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Stability testing is performed by UV spectrophotometry therefore audit trail is not required.
7.	Documents for the procurement of drug substance with approval from DRAP is required.	We have procured omeprazole sodium lyophilized ready to fill powder our own Semi-basic facility.
8.	Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	The firm has not submitted the details of reconstitution diluents with which dilution was carried.
9.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Compatibility studies were not provided with required diluents.

Evaluation by PEC:

<table>
<tr><th>Sr. No.</th><th>Decision of 313th meeting of RB</th><th>Response by the firm</th></tr>
<tr><td>1.</td><td>Justification of adopting UV-visible spectrophotometric method for assay testing of applied formulation.</td><td>• As we have the facility for semi basic preparation & we are lyophilizing the omeprazole and conduct the testing on HPLC.
• In Omeprazole 40 mg Injection (commercial batch) we are filling the same lyophilized powder tested in our quality control laboratory.
• We performed the final month Stability testing on HPLC. Testing for 36th month is attached in Annexure I.</td></tr>
<tr><td>2.</td><td>Submission of results of in-use stability studies of the drug product to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.</td><td>Testing after reconstitution shows satisfactory results
<table>
<tr><th>Reconstituted Diluent</th><th>Storage Condition</th><th>In-Use Shelf Life</th></tr>
<tr><td rowspan="2">NaCl 0.9% solution</td><td>2 – 8 ºC</td><td>24 Hours</td></tr>
<tr><td>25 ºC</td><td>12 Hours</td></tr>
</table>
</td></tr>
</table>

		Testing Reports with brief summary of results are attached in Annexure II.
3.	Submission of compatibility studies for the dry powder for injections to be performed as per the instructions provided in individual label of the drug product.	Omeprazole Dry Powder for Injection in reconstituted with 10ml of NaCl 0.9% solution and shows satisfactory results after 8 hours under storage condition 2 – 8 ºC. Testing Reports are attached in Annexure III
4.	Capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals Pvt. Ltd.	Capacity Assessment of manufacturing and testing facility of M/s Vision Pharma has been carried out.

Decision of 321st meeting of Registration Board: Registration Board noted the fact that firm had initially submitted stability studies data by UV spectrophotometric method for Assay test, while HPLC method was adopted for the 36th month time point of long term stability studies hence Registration Board deferred the case for submission of batch release data of recently manufactured commercial batches by M/s Vision pharmaceuticals wherein assay testing shall be performed using HPLC method.

Sr. No.	Decision of 321st meeting of RB	Response by the firm
1	**Registration Board noted the fact that firm had initially submitted stability studies data by UV spectrophotometric method for Assay test, while HPLC method was adopted for the 36th month time point of long term stability studies hence Registration Board deferred the case for submission of batch release data of recently manufactured commercial batches by M/s Vision pharmaceuticals wherein assay testing shall be performed using HPLC method.**	The Standard Analytical Procedure for Omeprazole 40mg Injection & Analytical Reports Along with supporting data of **3** latest commercial batches of Omeprazole sodium 40mg Injection have been submitted with HPLC testing

S.no.	Batch no.	Manufacturing date
1.	22J079	09-2022
2.	22H033	08-2022
3.	22J038	09-2022

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The Board further decided that applicant will submit latest GMP inspection report/ GMP Certificate valid within last three years of finished drug product manufacturer before issuance of registration letter along with fee of Rs. 75000/- as pre-registration variation fee for revision of stability data as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

1694.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan.
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot # 22-23, Industrial triangle, Kahuta Road, Islamabad
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the firm	**M/s Carer pharmaceutical Industries:** The firm is granted new license on 18/03/2021. **M/s Vision Pharmaceuticals:** The firm is granted GMP certificate based on inspection conducted on 23-04-2019.
	Evidence of approval of manufacturing facility	**M/s Vision Pharmaceuticals:** The firm has provided sterile Dry powder injection vials (General).

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13450: 19-05-2021
	Details of fee submitted	PKR 50,000/-: 12-02-2021
	The proposed proprietary name / brand name	Desan 40mg IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Omeprazole sodium eq. to Omeprazole (as lyophilized powder) …….40mg
	Pharmaceutical form of applied drug	Lyophilized Powder for injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg powder for solution for infusion of M/s Sandoz Novartis (MHRA approved)
	For generic drugs (me-too status)	Risek Injection 40mg of M/s Getz Pharma Pakistan
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, Characterization, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module-III Drug Substance:	The firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2 °C / 65% ± 5% RH for 36 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols and report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and Risek 40mg Injection (B # 789P06) manufactured by M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
	Analytical method validation/verification of product	Firm has submitted analytical method validation report of drug substance. Firm has submitted analytical method validation report of applied product.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Semi-basic Plant (DML # 000806). Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.
API Lot No.	1702901 1702902 1702903
Description of Pack (Container closure system)	Glass vial
Stability Storage Condition	Real Time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Rapid 40mg I.V Injection

Batch No.	1803707	1803708	1803709
Batch Size	10,000 vials	10,000 vials	10,000 vials
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	03-2018	03-2018	03-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate issued by Additional Director DRAP, Islamabad. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has procured material from their semi basic manufacturing facility.

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

Sr. No.	Observations communicated	Response by the firm
1.	Analytical method verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	The firm has submitted analytical method verification report from M/s Vision Pharmaceuticals Pvt, Ltd. Islamabad.
2.	Certificate of analysis of both drug substance manufacturer and drug product manufacturer are required.	The firm has submitted COAs of 3 batches of omeprazole lyophilized powder. The firm stated that we have a combined QC of both Formulation (000517) and Semi-Basic (000806) facility having same equipment and analysts for both facilities.
3.	Pharmaceutical equivalence of the applied drug shall be established with the innovator / reference / comparator product and results of all the quality tests of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed.	The firm has performed pharmaceutical equivalence of the developed formulation Rapid 40mg Injection (B#2005707) and Risek 40mg Injection (B # 789P06) manufactured by M/s GETZ Pharma. Quality tests of both products including physical appearance, solubility, water content, pH and assay were compared.
4.	Scientific justification is required for performing assay testing by UV method instead of HPLC method.	As the stability studies of the Bulk lyophilized material is performed by the Bulk manufacturer in the same QC lab with the same instrument (on HPLC) so just for verification purpose we performed the stability of the said product by UV. The firm has not submitted stability study data performed by HPLC alongwith raw data sheets, chromatograms and summary data sheets.
5.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	The firm has submitted copy of batch manufacturing record of 3 batches for which stability studies were carried out.
6.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Stability testing is performed by UV spectrometry therefore audit trail is not required.
7.	Documents for the procurement of drug substance with approval from DRAP is required.	We have procured omeprazole sodium lyophilized ready to fill powder our own Semi-basic facility.
8.	Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use	The firm has not submitted the details of reconstitution diluents with which dilution was carried.

	storage statement and in-use shelf-life shall be provided.	
9.	Compatibility studies for the dry powder for injections and dry powder for suspension shall be performed as per the instructions provided in individual label of the drug product.	Compatibility studies were not provided with required diluents.

Evaluation by PEC:

Sr. No.	Decision of 313th meeting of RB	Response by the firm
1.	Justification of adopting UV-visible spectrophotometric method for assay testing of applied formulation.	• As we have the facility for semi basic preparation & we are lyophilizing the omeprazole and conduct the testing on HPLC. • In Omeprazole 40 mg Injection (commercial batch) we are filling the same lyophilized powder tested in our quality control laboratory. • We performed the final month Stability testing on HPLC. Testing for 36th month is attached in Annexure I.
2.	Submission of results of in-use stability studies of the drug product to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life.	Testing after reconstitution shows satisfactory results **Reconstituted Diluent** | **Storage Condition** | **In-Use Shelf Life** NaCl 0.9% solution | 2 – 8 ºC | 24 Hours 25 ºC | 12 Hours Testing Reports with brief summary of results are attached in Annexure II.
3.	Submission of compatibility studies for the dry powder for injections to be performed as per the instructions provided in individual label of the drug product.	Omeprazole Dry Powder for Injection in reconstituted with 10ml of NaCl 0.9% solution and shows satisfactory results after 8 hours under storage condition 2 – 8 ºC. Testing Reports are attached in Annexure III
4.	Capacity assessment of manufacturing and testing facility of M/s Vision Pharmaceuticals Pvt. Ltd.	Capacity Assessment of manufacturing and testing facility of M/s Vision Pharma has been carried out.

Decision of 321st meeting of Registration Board: Deferred for submission of data of recently manufactured commercial batches in which assay testing has been performed using HPLC method.

Sr. No.	Decision of 321st meeting of RB	Response by the firm
1	**Deferred for submission of data of recently manufactured commercial batches in which assay testing has been performed using HPLC method.**	The Standard Analytical Procedure for Omeprazole 40mg Injection & Analytical Reports Along with supporting data of **3** latest commercial batches of Omeprazole sodium 40mg Injection have been submitted with HPLC testing S.no. Batch no. Manufacturing date 1. 22J079 09-2022 2. 22H033 08-2022 3. 22J038 09-2022

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The Board further decided that applicant will submit latest GMP inspection report/ GMP Certificate valid within last three years of finished drug product manufacturer before issuance of registration letter.**
- **The Board further decided that applicant will submit latest GMP inspection report/ GMP Certificate valid within last three years of finished drug product manufacturer before issuance of registration letter along with fee of Rs. 75000/- as pre-registration variation fee for revision of stability data as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

Agenda of Evaluator PEC-VIII

Case No. 01: Paracetamol Priority Case:

1695	**Name, address of Applicant / Marketing Authorization Holder**	M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sundar Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sundar Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	GMP Certificate issued on 28-03-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000782 (Formulation) renewed on 03-02-2019 which the approved sections are mentioned including section namely Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26329 dated 19-09-2022.
	Details of fee submitted	PKR 30000 dated: 18-10-2022 bearing Deposit Slip No. 968710443987
	The proposed proprietary name / brand name	**PYTOL-X Tablet (665 mg)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended release tablet contains: Paracetamol … 665mg USP Specs.
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OSTEOMOL 665 PARACETAMOL modified release Film **Coated tablet** TGA Australia.
	For generic drugs (me-too status)	Panadol-XR M/s GSK Paksitan Limited, Karachi.
	Name and address of API manufacturer.	**Paracetamol (B.P):** M/s Citi Pharma Limited, 3km, Head Balloki Road, Bhai Pheru, Dist. Kasur, Paksitan DML No. 000512 GMP Certificate No .(Not legible) issued on 19-03-2019
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 60 months. **(Batch No. PGP14-37, PGP14-38, PGP14-39)**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against Panadol Extended Release 665mg Tablets by performing quality tests including Identification, weight variation, Hardness, Assay, Dissolution. CDP has been performed against the same brand that is Panadol Extended Release 665mg Tablets Batch No. 2S6L manufacturing date December 2021 in, Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Paracetamol:** M/s Citi Pharma Limited, 3km, Head Balloki Road, Bhai Pheru, Dist. Kasur, Paksitan DML No. 000512 GMP Certificate No.(Not legible) issued on 19-03-2019		
API Lot No.	**PGP21-549**		
Description of Pack (Container closure system)	The proposed pack size of PYTOL-X Tablet 665 mg is 2x 10's in Alu—Alu Blister/Aluminum File.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, (Months) Real Time: 0, 3, (Months)		
Batch No.	AER-001	AER-002	N/A
Batch Size	5000 TABLETS	5000 TABLETS	N/A
Manufacturing Date	02-2022	02-2022	N/A
Date of Initiation	15-02-2022	15-02-2022	N/A
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Not Submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** M/s Citi Pharma Limited, 3km, Head Balloki Road, Bhai Pheru, Dist. Kasur, Paksitan DML No. 000512 **GMP Certificate No.(Not legible)** issued on 19-03-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not Required**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with summary data sheets , however, the chromatograms, raw data sheets are not submitted at every point of sampling/testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Following Documents are found deficient:

1. The GMP certificate of API manufacturer is issued on 19-03-2019, therefore, provide updated legible copy of GMP certificate of API manufacture in the light of guidance document.
2. Firm has applied for extended release un-coated tablets while the innovator Product OSTEOMOL 665 PARACETAMOL is modified release Film Coated tablet , therefore, submit evidence of un-coated tablet (Paracetamol 665mg) in Relevant Regulatory authorities.

3. Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator / reference product.
4. Provide Proposed Pack Size of Product.
5. The chromatograms, raw data sheets are not submitted at every point of sampling/testing.
6. Justification shall be submitted for same reading throughout the stability studies of both chambers as per submitted data logger record.

Reply of the Firm :

Sr No	Deficiencies/Short-coming	Answers
1	Provide updated legible copy of GMP certificate of API manufacturer.	Updated GMP Copy of API manufacturer has been attached here
2	Evidence of approval of applied formulation in reference regulatory authorities as defined by the registration Board shall be submitted. As the applied formulation in reference regulatory authorities is approved as "Film coated" tablets while the applicant has applied as un-coated tablets.	It is a typographical mistake to written in composition, Product has been formulated as film coated tablet In process testing record at film stage, filled BMR has been attached here
3	Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator/ reference product.	Qualitative Composition of Pytol-x is same as Innovator Product so Compatibility studies has been not performed Formulation of reference product has been attached here.
4	The chromatograms, raw data sheets shall be submitted for every point of sampling/testing during stability study.	chromatograms, raw data sheets for every point of sampling/testing during stability study has been attached here
5	Justification shall be submitted for same reading (Temperature & Humidity) throughout the stability studies of both chambers as per submitted data logger record.	Stability chamber 21 CFR Compliance software Audit trail has been attached here which shows all changes with date and time

Decision: Registration Board deferred the case for following reasons:

i. **The applicant shall submit detail of measures adopted by other countries (whether RRA or non-RRA) to mitigate the risk of toxicity associated with over-dose of above-mentioned product.**
ii. **The applicant shall also submit detail of practicable measures which will be adopted after grant of marketing authorization to prevent the risk of toxicity associated with over-dose of above-mentioned product.**

Case No. 02: NEW LICENSE / NEW SECTION:

1696	**Name, address of Applicant / Marketing Authorization Holder**	M/s Medasia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate Risalpur.
	Name, address of Manufacturing site.	M/s Medasia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate Risalpur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of DML No. 000690 (Formulation) issued on 10-11-2021 along with covering letter on which the

		approved sections are mentioned including section namely Tablet (General).
	Evidence of approval of manufacturing facility	Firm has submitted copy of DML No. 000690 (Formulation) issued on 10-11-2021 along with covering letter on which the approved sections are mentioned including section namely Tablet (General).
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32617 dated 14-11-2022
	Details of fee submitted	PKR 30000 dated: 26.10.2022 bearing Deposit Slip No. 76509063897
	The proposed proprietary name / brand name	**MOXASIA TABLET (400mg)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Moxifloxacin as HCL ….. 400mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	1's in ALU-ALU Blister
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Molox 400 mg tablet by M/s CCL Pharma, Lahore. Registration No. 042716
	Name and address of API manufacturer.	Moxifloxacin HCL (USP): Sheer Jee Laboratory Private Limited, (Subsidery of Mankind Pharma Limited, C-24 & 25, Riico Industrial Area, Sontanala, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **(Batch no. MXYSQ005, MXYSQ006, MXYSQ007)**

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Moxiget 400 mg Tablet of M/s Getz Pharma (Pvt) Ltd, Krachi Batch No. 224C31 by performing quality tests including Identification, uniformity of dosage form, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is Moxiget 400 mg Tablet of M/s Getz Pharma (Pvt) Ltd, Krachi Batch No. 224C31 in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	Moxifloxacin HCL (USP): Sheer Jee Laboratory Private Limited, (Subsidery of Mankind Pharma Limited, C-24 & 25, Riico Industrial Area, Sontanala, India		
API Lot No.	**Not Provided**		
Description of Pack (Container closure system)	The proposed pack size of Pixiz Tablet 100/10mg is 1x14's in Alu—Alu Blister.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3,6 (Months)		
Batch No.	001	002	003
Batch Size	1000 TABLETS	1000 TABLETS	1000 TABLETS
Manufacturing Date	10- 2021	10- 2021	10- 2021
Date of Initiation	15-10-2021	15-10-2021	15-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	• Medasia Pharma is a new license facility hence no such inspection has been conducted.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	. GMP certificate No. DC-I/A-I/WHO-GMP/2019/203 dated 07/2-19 valid till three years
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• **Not Provided**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Not Submitted**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Not Submitted**

Evaluation by PEC:

Following Documents are found deficient:

1. Provide valid GMP certificate of API manufacturer.
2. In the standard testing method for assay testing of API Moxifloxacin HCL (USP) the preparation of diluent and Mobile Phase is not done as specified in the USP monograph.
3. USP Specified test namely Microbial Enumeration test and enantiomeric impurity are performed by DS manufacturer in COA but not in stability test reports of API batches.
4. Specifications of excipients are not mentioned. The excipients used are different from the innovator Product (MHRA), therefore, submit compatibility studies .
5. The CDP and test reports are un-signed.
6. Uniformity of content test is USP specified test but is not performed during stability of Drug Product.
7. The HPLC conditions (injection volume and flow rate) are different from the ones specified in USP in assay testing of Drug Product.
8. Chromatograms supporting the stability studies are not submitted for every point of stability testing.
9. Compliance Record of HPLC software 21CFR & audit trail reports on product testing & Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted.
10. BMR of trial batches is not submitted.
11. Specify the API Lot No being used in trial batches along with Documents for the procurement of API with approval from DRAP (in case of import).

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

1697	**Name, address of Applicant / Marketing Authorization Holder**	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Evidence of approval of manufacturing facility	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 26862 Date: 22/9/2022
	Details of fee submitted	PKR 30000 dated: 16-09-2022 . SLIP No. 003359682193
	The proposed proprietary name / brand name	**BRIPROFEN 200 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Ibuprofin …… 200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's, 20's,30's,100's,200's Blister (1000's Jar Pack)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	**Brand Name:** Pando (200mg) Tablet **Registration holder:** M/s Efroze Pharma(Pvt) Ltd , Karachi. **Registration Number:** 012062
	Name and address of API manufacturer.	**Ibuprofen (BP) :** M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. **(Batch No. ZIBU11-001, ZIBU11-002, ZIBU11-003)**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of

		specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have not been established/submitted with innovator Product, **but with Brufen 200 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi.** **CDP has been performed against the same brand that is** Brufen 200 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi **instead of Innovator / Reference Product** in Acid media (0.1N HCl),), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory(>50%).
	Analytical method validation/verification of product	Firm has submitted **report of verification studies of analytical method (BP)** of drug substance. Firm has submitted report of verification of analytical method (USP) for the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**		
API Lot No.	**API batch No. Zibu21-029**		
Description of Pack (Container closure system)	10's / Jar Pack Alu-PVC Blister Pack in unit carton with leaflet		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B-1	T-B-2	T-B-3
Batch Size	1086 Tablets	1086 Tablets	1086 Tablets
Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	03-05-2021	03-05-2021	03-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not required.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	For march 2021 while the stability is initiated in May 2021.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Submitted.**

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

Evaluation by PEC:

1. GMP certificate of API manufacturer is issued on 22-05-2019.
2. Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted
3. Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.
4. Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms
5. Detail of equipment's/machinery as used in Product Development if not submitted.
6. Product Assay method as mentioned in Product Development is different from the one specified in (USP).
7. Specificity Method and test reports are not submitted for Drug Product.
8. %RSD is not calculated for tests performed for Drug Product analytical method verification.
9. In BMR check points include i.e. average tablet size to be 460mg, and target weight is also 460mg while the Tablet is of 200mg.
10. Chromatograms submitted along with stability data sheets in Briprofin 200mg tablets, date of data processing/acquiring is mentioned as 11-03-2021 while the stability is initiated in May 2021.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

1698	**Name, address of Applicant / Marketing Authorization Holder**	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s British Pharmaceutical (Pvt) Ltd, 23 km, Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Evidence of approval of manufacturing facility	Copy of Valid DML No. 000729 (Formulation) renewed on 22-06-2021 along with covering letter is provided.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26861 Date: 22/9/2022
	Details of fee submitted	PKR 30000 dated: 16-09-2022 . SLIP No. 0137541252
	The proposed proprietary name / brand name	**BRIPROFEN 400 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet contains: Ibuprofin …… 400mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's, 20's,30's,100's,200's Blister (1000's Jar Pack)

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved, (Ibuprofin 400mg by The Boots Company PLC 1 Thane Road West Nottingham NG2 3AA)
	For generic drugs (me-too status)	**Brand Name:** Zafen (400mg) Tablet **Registration holder:** M/s Xenon Pharma , Lahore. **Registration Number:** 050650
	Name and address of API manufacturer.	**Ibuprofen (BP) :** M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. **(Batch No. ZIBU11-001, ZIBU11-002, ZIBU11-003)**
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have not been established/submitted with innovator Product, **but with Brufen 400 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi.** **CDP has been performed against the same brand that is** Brufen 400 mg Tablet of M/s Abbot Pharmaceutical Pakistan Ltd, Karachi **instead of Innovator / Reference Product** in Acid media (0.1N HCl),), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory(>50%).
	Analytical method validation/verification of product	Firm has submitted **report of verification studies of analytical method (BP)** of drug substance. Firm has submitted report of verification of analytical method (USP) for the drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**		
API Lot No.	**API batch No. Zibu21-029**		
Description of Pack (Container closure system)	10's / Jar Pack Alu-PVC Blister Pack in unit carton with leaflet		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-B-1	T-B-2	T-B-3
Batch Size	1162 Tablets	1162 Tablets	1162 Tablets
Manufacturing Date	May 2021	May 2021	May 2021
Date of Initiation	05-05-2021	05-05-2021	05-05-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Zenith Chemical Industry Lahore GMP Certificate No. 141/2019-DRAP(AD-813875-228) dated : **22-05-2019**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not required.**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Chromatograms, Raw data sheets, summary data sheets are submitted only at **0 months (May 2021)**
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**Submitted.**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	**Submitted.**

Evaluation by PEC:

1. GMP certificate of API manufacturer is issued on 22-05-2019.
2. Analytical assay method verification test reports/results of API by both Drug Substance and Drug Product manufacturer are not submitted
3. Provide detail of excipients along with specifications along with compatibility studies as the excipients used in Product development are different from the ones of innovator product.
4. Uniformity of Dosage forms is a USP Specified test for Drug Product but in stability study reports/results it is not performed and is not mentioned in Stability data test reports of 400mg tablet and both Uniformity of Dosage forms
5. Detail of equipment's/machinery as used in Product Development is not submitted.
6. Product Assay method as mentioned in Product Development is different from the one specified in (USP).
7. Specificity Method and test reports are not submitted for Drug Product.
8. %RSD is not calculated for tests performed for Drug Product analytical method verification.
9. Detail of excipients along with specifications is not submitted as the excipients used in Product development are different from the ones in innovator product.
10. Chromatograms, Raw data sheets, summary data sheets are submitted only at **0 months (May 2021).**

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six (06) months.

1699	**Name, address of Applicant / Marketing Authorization Holder**	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of covering letter of renewal of DML No. 000106(Formulation) dated 30-06-2020 on which the approved sections are mentioned including section namely Tablet (General).
	Evidence of approval of manufacturing facility	Firm has submitted copy of covering letter of renewal of DML No. 000106(Formulation) dated 30-06-2020.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33306 dated 13-12-2021
	Details of fee submitted	PKR75000 dated: 26.11.2021 bearing Deposit Slip No. 33798086745
	The proposed proprietary name / brand name	**PIXIZ TABLET 50mg/10mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	PIXIZ TABLET 50mg/10mg Each film coated tablet contains: Losartan Potassium … 50mg Amlodipine Besylate equivalent to Amlodipine ……...… 10mg Tabros Specs.
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Losartan Potassium: Angiotensin II Receptor Antagonist Amlodipine Besylate: Calcium channel blocker
	Reference to Finished product specifications	Tabros Specifications
	Proposed Pack size	1x14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LosAmlo Tablet 50mg/10mg Krka d.d Germany/Slowenien. **( ).** Also available n three EMA member states i.e, Solvakia, Bulgaria & Hungary
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**Losartan Potassium: USP** Zhejiang Huahai Pharmaceutical Co., Ltd. Chunnan, Duqiao, Linhai Zhejiang, China **Amlodipine Besylate B.P.** M/s SMRUTHI ORGANICS LIMITED

		A-27, MIDC, CHINCHOLI, TAL-MOHOL, SOLAPUR 413255 MAHARASHTRA STATE, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is LosAmlo Tablet 50/10mg by Boehringer Ingelheim, by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is LosAmlo Tablet 50/10mg by KRKA, d.d., Novo mesto, Germany in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	**Losartan Potassium: USP** Zhejiang Huahai Pharmaceutical Co., Ltd. Chunnan, Duqiao, Linhai Zhejiang, China **Amlodipine Besylate B.P.** M/s SMRUTHI ORGANICS LIMITED A-27, MIDC, CHINCHOLI, TAL-MOHOL, SOLAPUR 413255 MAHARASHTRA STATE, INDIA.
API Lot No.	Losartin Potassium Batch No. C5458-18-017

	Amlodipine Besylate – Batch No. AMBC 014/19		
Description of Pack (Container closure system)	The proposed pack size of Pixiz Tablet 50/10mg is 1x14's in Alu—Alu Blister.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6(Months)		
Batch No.	TR001-2/PIZ	TR002-2/PIZ	TR003-2/PIZ
Batch Size	1200 TABLETS	1200 TABLETS	1200 TABLETS
Manufacturing Date	June 2021	June 2021	June 2021
Date of Initiation	19-07-2021	19-07-2021	19-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	•
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Losartan Potassium** M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Valid till 15.10.2024. The firm has submitted copy of GMP certificate for **Amlodipine Besylate** M/s SMRUTHI ORGANICS LIMITED Valid till 13.11.2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Losartan Potassium** The firm has imported 3Kg API consignment Zhejiang Huahai Pharmaceutical Co., Ltd. China bearing invoice number HH20200610R dated 22-06-2020. **Amlodipine Besylate** • The firm has imported 50Kg commercial consignment of API from SMRUTHI ORGANICS LIMITED India, bearing invoice number E-150 dated December 27, 2019 signed by ADC on 03-01-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
Evaluation by PEC:		
Following Documents are found deficient:		

1. In the standard testing method for testing of DS Losartan Potassium (USP) ,the wavelength used by DS Manufacturer is 215nm while the wavelength used by the manufacturer of Product is 220nm and the wavelength specified in the USP is different.
2. Stability data of Data Product provided is of three(03) months rather than 06 months.

Reply of Observations:

S. No.	Deficiencies / Short-comings	Justification
1.	In the standard testing method for testing of testing of DS Losartan potassium (USP), the wavelength used by DS manufacturer is 215nm while the wavelength used by the manufacturer of drug product is 220nm and the wavelength specified in the USP is different.	We have been performed Analysis / testing of Losartan potassium Drug Substance as per USP monograph and analytical method verification studies as per ICH guidelines, supporting documents are being attached for your kind perusal: i. Drug substance analytical method as per USP. ii. Drug substance analytical method verification studies in accordance with USP. iii. Revised Certificate of analysis of drug substance analyzed by USP method.
2.	Stability data of product provided is of three (03) months rather than 06 months.	Initially we have submitted CTD dossier application with 3 months stability data, later on again we have submitted 6 months stability data accordingly vide letter DRAP/TAB-REG/03-22, dated March 2,2022. Copy of acknowledgment letter is attached for your ready reference.

Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.

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

1700	**Name, address of Applicant / Marketing Authorization Holder**	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt. Ltd. L-20/B, Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of covering letter of renewal of DML No. 000106(Formulation) dated 30-06-2020 on which the approved sections are mentioned including section namely Tablet (General).
	Evidence of approval of manufacturing facility	Firm has submitted copy of covering letter of renewal of DML No. 000106(Formulation) dated 30-06-2020.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 33306 dated 13-12-2021

	Details of fee submitted	PKR75000 dated: 26.11.2021 bearing Deposit Slip No. 7379013255
	The proposed proprietary name / brand name	**PIXIZ TABLET 50mg/5mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	PIXIZ TABLET 50mg/5mg Each film coated tablet contains: Losartan Potassium … 50mg Amlodipine Besylate equivalent to Amlodipine ……...… 5mg Tabros Specs.
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Losartan Potassium: Angiotensin II Receptor Antagonist Amlodipine Besylate: Calcium channel blocker
	Reference to Finished product specifications	Tabros Specifications
	Proposed Pack size	1x14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LosAmlo Tablet 50mg/10mg Krka d.d Germany/Slowenien. **( ).** Also available n three EMA member states i.e, Solvakia, Bulgaria & Hungary
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**Losartan Potassium: USP** Zhejiang Huahai Pharmaceutical Co., Ltd. Chunnan, Duqiao, Linhai Zhejiang, China **Amlodipine Besylate B.P.** M/s SMRUTHI ORGANICS LIMITED A-27, MIDC, CHINCHOLI, TAL-MOHOL, SOLAPUR 413255 MAHARASHTRA STATE, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 6 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control,

		process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the brand leader that is LosAmlo Tablet 50/5mg by Boehringer Ingelheim, by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is LosAmlo Tablet 50/5mg by KRKA, d.d., Novo mesto, Germany in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA

Manufacturer of API	**Losartan Potassium: USP** Zhejiang Huahai Pharmaceutical Co., Ltd. Chunnan, Duqiao, Linhai Zhejiang, China **Amlodipine Besylate B.P.** M/s SMRUTHI ORGANICS LIMITED A-27, MIDC, CHINCHOLI, TAL-MOHOL, SOLAPUR 413255 MAHARASHTRA STATE, INDIA.		
API Lot No.	Losartin Potassium Batch No. C5458-18-017 Amlodipine Besylate – Batch No. AMBC 014/19		
Description of Pack (Container closure system)	The proposed pack size of Pixiz Tablet 50/5mg is 1x14's in Alu—Alu Blister.		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6(Months)		
Batch No.	TR003-1/PIZ	TR003-2/PIZ	TR003-3/PIZ
Batch Size	1200 TABLETS	1200 TABLETS	1200 TABLETS
Manufacturing Date	June 2021	June 2021	June 2021
Date of Initiation	19-07-2021	19-07-2021	19-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	•
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Losartan Potassium** M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Valid till 15.10.2024.

		The firm has submitted copy of GMP certificate for **Amlodipine Besylate** M/s SMRUTHI ORGANICS LIMITED Valid till 13.11.2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Losartan Potassium** The firm has imported 3Kg API consignment Zhejiang Huahai Pharmaceutical Co., Ltd. China bearing invoice number HH20200610R dated 22-06-2020. **Amlodipine Besylate** • The firm has imported 50Kg commercial consignment of API from SMRUTHI ORGANICS LIMITED India, bearing invoice number E-150 dated December 27, 2019 signed by ADC on 03-01-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Following Documents are found deficient:

3. In the standard testing method for testing of DS Losartan Potassium (USP) ,the wavelength used by DS Manufacturer is 215nm while the wavelength used by the manufacturer of Product is 220nm and the wavelength specified in the USP is different.
4. Stability data of Data Product provided is of three(03) months rather than 06 months.

Reply of Observations:

S. No.	Deficiencies / Short-comings	Justification
1.	In the standard testing method for testing of testing of DS Losartan potassium (USP), the wavelength used by DS manufacturer is 215nm while the wavelength used by the manufacturer of drug product is 220nm and the wavelength specified in the USP is different.	We have been performed Analysis / testing of Losartan potassium Drug Substance as per USP monograph and analytical method verification studies as per ICH guidelines, supporting documents are being attached for your kind perusal: i. Drug substance analytical method as per USP. ii. Drug substance analytical method verification studies in accordance with USP. iii. Revised Certificate of analysis of drug substance analyzed by USP method.
2.	Stability data of product provided is of three (03) months rather than 06 months.	Initially we have submitted CTD dossier application with 3 months stability data, later on again we have submitted 6 months stability data accordingly vide letter DRAP/TAB-REG/03-22, dated March 2,2022. Copy of acknowledgment letter is attached for your ready reference.

Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.

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

Agenda of Evaluator PEC-IX

1701.	Name and address of manufacturer/ Applicant	M/s Alfalah Pharma (pvt), Ltd, 12-Km, Sheikhupura Road, Lahore (contract giver) (DML No. 000461) M/s Synchro Pharmaceuticals, 77-Industrial Estate, Kot Lakhpat, Lahore (Contract Acceptor) (DML No. 000575) Dry Powder Injection (Cephalosporin)
	Brand Name + Dosage Form + Strength	ALFAXON 500mg Injection (IM)
	Composition	Each Vial Contains; Ceftriaxone (as sodium) ….500mg
	Diary No. Date of R & I & fee	Dy. No. 16422 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0795642 dated 06-03-2019, endorsed on 07.03.2019. Duplicate Dossier submitted vide Dy. No. 32790 dated 15.11.2022.
	Pharmacological Group	Third-generation cephalosporins. ATC Code: J01DD04
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	USP Specification
	Pack size & Demanded Price	01's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg, 500mg and 1g Powder for Solution for Injection and 2g Pwder for Solution for Injection or Infusion - PL 22805/0001, 3-5 MHRA Approved.
	Me-too status	Rociphen Injection 500mg IM Reg. No. 008434 M/s Martin Dow.
	GMP status	Last inspection conducted on 22.01.21. GMP status is good. GMP certificate valid till 21.01.2023 is submitted
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
1702.	Name and address of manufacturer/ Applicant	M/s Perk Pharma (Pvt.) Ltd. Plot No. 197/1-B Main Road, Industrial Estate, Gadoon. (contract giver) (DML No. 000857) M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle, Kahuta Road Islamabad (Contract Acceptor) (DML No. 000296) LVP
	Brand Name + Dosage Form + Strength	LINZEPERK 600mg/300mL (IV)
	Composition	Each Vial Contains; Linezolid …..600mg
	Diary No. Date of R & I & fee	Dy. No. 16811 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0840478 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antibacterials. ATC Code: J01XX08
	Type of Form	Form 5 (Contract)
	Finished product Specification	Manufacturer's Specifications.

	Pack size & Demanded Price	300mL x 1's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Zyvox 2 mg/ml solution for infusion, 300 ml infusion bags contain 600 mg linezolid. MHRA Approved
	Me-too status	Nezkil 600 mg Infusion, Reg. No. 048804 M/s S.J. & G. Fazul Ellahi (Pvt.) Ltd. Karachi
	GMP status	Last inspection conducted on 08.03.2021. GMP status is good.
	Remarks of the Evaluator	Section Approval letter (for LVP) of M/s Bio Labs is required.
	Decision: Deferred for evidence of availability of filling line for fill volume of parenteral solutions upto 300ml in M/s Bio-Labs (Pvt.) Ltd. Islamabad.	
1703.	Name and address of manufacturer/ Applicant	M/s Medisave Pharmaceuticals 578-579 Sundar Industrial Estate Sundar Raiwind Road Lahore. (contract giver) (DML No. 000681) M/s Stallion Pharmaceuticals (Pvt.) Ltd. Plot No. 581, Sundar Industrial Estate Lahore (Contract Acceptor) (DML No. 000783) Dry Powder Injection (Penicillin) Section
	Brand Name + Dosage Form + Strength	TAZOSAVE 4.5g (IV)
	Composition	Each Vial Contains; Piperacillin (as piperacillin sodium)…..4g Tazobactam (as tazobactam sodium)….0.50g
	Diary No. Date of R & I & fee	Dy. No. 14984 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0536167 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Combinations of penicillins, incl. beta-lactamase inhibitors. ATC Code: J01CR05
	Type of Form	Form 5 (Contract)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PIPERACILLIN/TAZOBACTAM 4 G/ 0.50 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 28176/0046 MHRA APPROVED.
	Me-too status	Tanzo 4.5gm Inj Reg. No. 039439 M/s Bosch Pharmaceuticals Karachi..
	GMP status	Last inspection conducted on 22.11.2018.
	Remarks of the Evaluator	i. Section approval letter of carbapenem section is provided, penicillin section approval letter is required. ii. Latest GMP inspection report/GMP certificate of M/s Stallion is required.
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt.) Ltd	
1704.	Name and address of manufacturer/ Applicant	M/s Medisave Pharmaceuticals 578-579 Sundar Industrial Estate Sundar Raiwind Road Lahore. (contract giver) (DML No. 000681) M/s Stallion Pharmaceuticals (Pvt.) Ltd. Plot No. 581, Sundar Industrial Estate Lahore (Contract Acceptor) (DML No. 000783) Dry Powder Injection (Carbapenem) Section
	Brand Name + Dosage Form + Strength	MEROSAVE 500mg (IV)
	Composition	Each Vial Contains; Meropenem (as Meropenem trihydrate)…..500mg

	Diary No. Date of R & I & fee	Dy. No. 14986 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0788765 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form 5 (Contract)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 500 MG AND 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION (MEROPENEM) - UK/H/4098/001-2/DC; PL 34985/0003-4 MHRA APPROVED.
	Me-too status	Meronem IV 500mg Injection Reg. No. 096203 M/s Pfizer Pakistan.
	GMP status	Last inspection conducted on 22.11.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/GMP certificate of M/s Stallion is required.
	Decision: Registration Board on basis of its decision of 312th meeting wherein applied formulation had already been approved for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, decided to approve instant application. • **Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**	
1705.	Name and address of manufacturer/ Applicant	M/s Medisave Pharmaceuticals 578-579 Sundar Industrial Estate Sundar Raiwind Road Lahore. (contract giver) (DML No. 000681) M/s Stallion Pharmaceuticals (Pvt.) Ltd. Plot No. 581, Sundar Industrial Estate Lahore (Contract Acceptor) (DML No. 000783) Dry Powder Injection (Carbapenem) Section
	Brand Name + Dosage Form + Strength	MEROSAVE 1g (IV)
	Composition	Each Vial Contains; Meropenem (as Meropenem trihydrate)…..1g
	Diary No. Date of R & I & fee	Dy. No. 14985 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0788766 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form 5 (Contract)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 500 MG AND 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION (MEROPENEM) - UK/H/4098/001-2/DC; PL 34985/0003-4 MHRA APPROVED.
	Me-too status	Meronem IV 1g Injection Reg. No. 096204 M/s Pfizer Pakistan.
	GMP status	Last inspection conducted on 22.11.2018.
	Remarks of the Evaluator	i. Latest GMP inspection report/GMP certificate of M/s Stallion is required. ii. Fee Slip of product Neostig having amount of Rs. 20,000/- is attached. Correct fee slip is required.

	Decision: Registration Board on basis of its decision of 312th meeting wherein applied formulation had already been approved for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, decided to approve instant application. • **Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**	
1706.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845) M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590) Liquid Injectable Ampoule/Vial General
	Brand Name + Dosage Form + Strength	Revalp 500mg/5ml Ampoule (IV)
	Composition	Each 5mL Ampoule Contains; Valproate Sodium equivalent to Valproic acid…500mg
	Diary No. Date of R & I & fee	Dy. No. 15176 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0731650 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	ANTIEPILEPTICS, Fatty acid derivatives ATC Code: N03AG01
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5's & 10's As per SRO.
	Approval status of product in Reference Regulatory Authorities	Couldn't be verified for applied product.
	Me-too status	Epival IV Injection Reg. No. 023349 M/s Abbott Laboratories
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. The Evidence of RRA provided (Depacon USFDA) is discontinued. Evidence of product in other RRA is observed to be of 3ml, 4ml and 10ml. Justification, or revision along with requisite fee is required (Full Fee). ii. In-house specifications are mentioned. Product monograph is available in pharmacopoeia. Justification or correction along with requisite fee is required. The firm vide letter No. GP-101/22 dated 24.11.2022 has submitted reply that specifications of applied product are USP Specifications. The firm has submitted fee Rs. 7500/- for revision of specs vide slip No. 050861946601 The firm has submitted reference of USFDA approved product Valproate Sodium Injection USP 500mg/5ml in vial. Applied product is a 5mL ampoule. In MHRA Sodium Valproate is approved in ampoules of 10mL and 4mL, having strength of 1000mg and 400mg.

		In Austria Convulex 100 mg/ml - solution for injection is licensed vide license No. 1-25002. The label claim of this product is reproduced below; "1 ampoule with 5 ml solution for injection contains 500 mg sodium valproate (equivalent to 433.9mg valproic acid)." Capacity assessment inspection report of M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore presented in 295th meeting of Registration Board wherein Board decided to allow contract manufacturing from M/s Novamed Pharmaceuticals Pvt Ltd, 28km Ferozepur Road, Lahore for following sections: • Dry Powder Injection (Cephalosporin) Section • Dry Powder Suspension (Cephalosporin) Section • Capsule (Cephalosporin) Section • General Liquid Injection (Ampoule) • General Liquid Injection Vials (SVP)
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.	
1707.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845) M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590) Liquid Injectable Ampoule/Vial General
	Brand Name + Dosage Form + Strength	Mecogen 500mcg/1mL (IV/IM)
	Composition	Each 1mL Ampoule Contains; Mecobalamin…….500mcg
	Diary No. Date of R & I & fee	Dy. No. 15178 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0731648 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	In House
	Pack size & Demanded Price	10's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	METHYCOBAL 500µg injection PDMA Japan Approved.
	Me-too status	Reli-cobal Injection 500mcg Reg. No. 083440 M/s Reliance Pharma
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit fee Rs. 7500/- for change of specifications as per notification No. 7-11/2012-B&A/DRAP dated 07.05.2021. **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.**	
1708.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845)

		M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590) Liquid Injectable Ampoule/Vial General
	Brand Name + Dosage Form + Strength	LEPSI 500mg/mL (IV)
	Composition	Each 5mL Ampoule contains; Levetiracetam (USP)….500mg
	Diary No. Date of R & I & fee	Dy. No. 15177 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0731649 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	LEVETIRACETAM 100 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION - PLGB 46447/0064 (5 mL vial) **contains 500mg** MHRA Approved.
	Me-too status	Lerace 500mg/5ml Injection Reg. No. 066949 M/s Hilton Pharma (Pvt) Ltd Karachi.
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. The products approved in RRA are mostly in Vial. 500mg/5ml ampoules are locally approved like Lerace 500mg/5ml In MHRA Levetiracetam 100 mg / mL Concentrate for solution for infusion is approved vide authorization No. PL 24598/0074 daetd 30.09.2020 in which both 5mL vial and ampoule are approved. The shelf life of Vials is 30 months whereas for ampoules is 18 months. ii. On Form-5. Lepsi 500mg/mL is mentioned with label that ml contains 100mg Levetiracetam **The firm vide letter No. GP-101/22 dated 24.11.2022 has submitted corrected Form-5 having Label as under;** **Each 5ml contains** **Levetiracetam…..500mg** Fee for correction of is not paid. The firm has submitted summary of accelerated and real time stability studies of product done by M/s Novamed Pharmaceuticals as per conditions of Zone IV A. The stability summary shows that product is stable for time upto 24 months.
	Decision: Approved. Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.	
1709.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845) M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590)

		General Liquid Injection Vial (SVP)
	Brand Name + Dosage Form + Strength	TERMIGEN 500mg Vial
	Composition	Each 100mL vial contains; Levofloxacin hemihydrate eq. to Levofloxacin …..500mg
	Diary No. Date of R & I & fee	Dy. No. 15181 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0731646 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA12
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	Not defined.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Levofloxacin 5 mg/ml Solution for Infusion - UK/H/2468/001/DC; PL 11204/0224 (100 mL and 50 mL) MHRA Approved.
	Me-too status	Leflox 500mg/100ml IV Infusion
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. Finished product specifications are not mentioned.
	Decision: Approved with Innovator's Specifications. Firm shall submit fee of Rs. 7500/- for change of specifications as per notification No. 7-11/2012-B&A/DRAP dated 07.05.2021. **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.**	
1710.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845) M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590) Liquid Injectable Ampoule/Vial General
	Brand Name + Dosage Form + Strength	TERMIGEN 250mg Vial
	Composition	Each 50mL vial contains; Levofloxacin hemihydrate eq. to Levofloxacin …..250mg
	Diary No. Date of R & I & fee	Dy. No. 15180 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0731647 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA12
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	Not defined.
	Pack size & Demanded Price	1's x 50mL. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Levofloxacin 5 mg/ml Solution for Infusion - UK/H/2468/001/DC; PL 11204/0224 (100 mL and 50 mL) MHRA Approved.
	Me-too status	Evaxosure 250mg IV Injection Reg. No. 075902 M/s Medisure.
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. Finished product specifications are not mentioned. ii. The 250mg infusion approved in MHRA has a volume of 50mL, whereas applied product has a volume of 100mL **The firm vide letter dated 24.11.2022 has informed that 100mL is a typographic error. The label claim is 250mg/50mL. The firm has paid fee**

		of Rs. 75000/- vide Slip No. 4067292594 for correction of formulation/label.
	Decision: Approved with Innovator's Specifications. Firm shall submit fee of Rs. 7500/- for change of specifications as per notification No. 7-11/2012-B&A/DRAP dated 07.05.2021. **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.**	
1711.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845) M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590) Liquid Injectable Ampoule/Vial General
	Brand Name + Dosage Form + Strength	Sterol-D 200,000IU (5mg/ml) IM
	Composition	Each 1mL Ampoule Contains; Vitamin D3…200,000IU
	Diary No. Date of R & I & fee	Dy. No. 15179 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0810048 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Vitamin D and analogues. ATC Code: Not found for parenteral preparation.
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	In-House
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 BON 200,000 IU/1 ml solution for injection IM ampoule ANSM France Approved.
	Me-too status	Reli-Chole 5mg Injection Reg. No. 083439 M/s Reliance Pharma
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit fee of Rs. 7500/- for change of specifications as per notification No. 7-11/2012-B&A/DRAP dated 07.05.2021. • **Registration Board further authorized its Chairman for issuance of registration letter upon satisfactory capacity assessment of manufacturing and testing facility of M/s Novamed Pharmaceuticals (Pvt.) Ltd.**	
1712.	Name and address of manufacturer/ Applicant	M/s Genetics Pharmaceuticals (Pvt.) Ltd. 539-A Sundar Industrial Estate Raiwind Road Lahore (contract giver) (DML No. 000845) M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract acceptor) (DML No. 000590) Liquid Injectable Ampoule/Vial General
	Brand Name + Dosage Form + Strength	Navilox 400mg/250ml (IV)
	Composition	Each 250mL Vial Contains; Moxifloxacin HCl……..400mg
	Diary No. Date of R & I & fee	Dy. No. 15182 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0810047 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	In-house specifications.

	Pack size & Demanded Price	250mL x 1's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Avelox 400 mg/250 ml solution for infusion MHRA Approved.
	Me-too status	Avelox Infusion Reg. No. 030851 M/s Bayer Pakistan (Pvt.) Ltd. Kot Lakhpat.
	GMP status	Last inspection conducted on 06.08.2021. GMP Certificate valid till 05.08.2023 is submitted.
	Remarks of the Evaluator	i. LVP Section approval of M/s Novamed is required is required. **The firm vide letter dated 24.11.2022 has submitted section approval letter of M/s Novamed Pharmaceuticals (Pvt)Ltd. DML No. 000590, the section approval letter mentions "Liquid Injectable Ampoule/Vial General" section**
	Decision: Deferred for provision of evidence of availability of manufacturing facility for applied fill volume.	
1713.	Name and address of manufacturer/ Applicant	M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract giver) (DML No. 000590) M/s Stallion Pharmaceuticals (Pvt.) Ltd. Plot No. 581, Sundar Industrial Estate Lahore (Contract Acceptor) (DML No. 000783) Dry Powder Injection Vial (Carbapenem)
	Brand Name + Dosage Form + Strength	Imitin Injection 500mg/ 500mg Injection (IV)
	Composition	Each Vial Contains; Imipenem ……...500mg Cilastatin (as Cilastatin Sodium)….500mg
	Diary No. Date of R & I & fee	Dy. No. 15222 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0841848 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Carbapenems ATC Code: J01DH51
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Imipenem 500 mg/Cilastatin 500 mg Powder for Solution for Infusion (imipenem, cilastatin sodium) - UK/H/3257/001/DC and UK/H/3436/001/DC;PL 15773/0829 and PL 15773/0834. MHRA Approved.
	Me-too status	Tienam 500mg IV Injection Reg. No. 014934 M/s OBS Healthcare (Pvt) ltd Karachi.
	GMP status	Last inspection conducted on 22.11.2018.
	Remarks of the Evaluator	i. The products approved in RRA are using hydrated imipenem, whereas in applied product anhydrous imipenem is being used. Clarification is required. ii. Latest GMP inspection inspection report/GMP certificate of M/s Stallion is required.
	Decision: Deferred for following; • **Observtaions on the applications of contract manufacturing from M/s Stallion Pharmaceuticals applied on form 5F.** • **Capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd. 581, Sundar Industrial Estate, Raiwind Road Lahore.**	

1714.	Name and address of manufacturer/ Applicant	M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract giver) (DML No. 000590) M/s Stallion Pharmaceuticals (Pvt.) Ltd. Plot No. 581, Sundar Industrial Estate Lahore (Contract Acceptor) (DML No. 000783) Dry Powder Injection Vial (Carbapenem)
	Brand Name + Dosage Form + Strength	PeneMed Injection 1gram (IV)
	Composition	Each Vial Contains; Meropenem (as Meropenem trihydrate)….. 1g
	Diary No. Date of R & I & fee	Dy. No. 15224 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0841847 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MEROPENEM 1 G POWDER FOR SOLUTION FOR INJECTION OR INFUSION - PL 51312/0003. MHRA Approved.
	Me-too status	Merostin 1gm Dry Powder Injection Reg. No. 080837 M/s Stallion Pharmaceuticals (Pvt.) Ltd. Lahore.
	GMP status	Last inspection conducted on 22.11.2018.
	Remarks of the Evaluator	i. Latest GMP inspection inspection report/GMP certificate of M/s Stallion is required.
	Decision: Registration Board on basis of its decision of 312th meeting wherein applied formulation had already been approved for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, decided to approve instant application. • **Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**	
1715.	Name and address of manufacturer/ Applicant	M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-KM, Ferozpur Road, Lahore-Pakistan (contract giver) (DML No. 000590) M/s Stallion Pharmaceuticals (Pvt.) Ltd. Plot No. 581, Sundar Industrial Estate Lahore (Contract Acceptor) (DML No. 000783) Dry Powder Injection Vial (Carbapenem)
	Brand Name + Dosage Form + Strength	PeneMed Injection 500mg (IV)
	Composition	Each Vial Contains; Meropenem (as Meropenem trihydrate)….. 500mg
	Diary No. Date of R & I & fee	Dy. No. 15223 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0841846 dated 05-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Carbapenems ATC Code: J01DH02
	Type of Form	Form-5 (Contract manufacturing)
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Meropenem 500 mg powder for solution for injection or infusion (meropenem trihydrate) - PL 41697/0001; UK/H/5288/001/DC. MHRA Approved.
	Me-too status	Merostin 500mg Dry Powder Injection Reg. No. 080836 M/s Stallion Pharmaceuticals (Pvt.) Ltd. Lahore.

	GMP status	Last inspection conducted on 22.11.2018.
	Remarks of the Evaluator	i. Latest GMP inspection inspection report/GMP certificate of M/s Stallion is required.
	Decision: Registration Board on basis of its decision of 312th meeting wherein applied formulation had already been approved for contract manufacturing from M/s Stallion Pharmaceuticals Pvt Ltd. on basis of Form 5F (CTD) of M/s Healthtek (Pvt) Ltd., Karachi as applicant, decided to approve instant application. • **Registration Board further authorized its Chairman for issuance of registration letters upon satisfactory capacity assessment of manufacturing and testing facility of M/s Stallion Pharmaceuticals (Pvt) Ltd., 581- Sundar Industrial Estate, Lahore.**	

Deferred Cases

1716.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma (Pvt) Ltd. Lahore (DML No. 000492) Tablet Section (Antibiotic, General)
	Brand Name +Dosage Form + Strength	Irofer-F chewable tablet
	Composition	Each tablet contains: Iron (III) hydroxide polymaltose complex eq to elemental iron……100mg Folic acid…….350mcg
	Diary No. Date of R& I & fee	Dy. No.7959; 21-6-2011; Rs.8,000/- (21-6-2011); Rs.12,000/- (09-10-2015)
	Pharmacological Group	Haematinitic, Iron in combination with folic acid ATC Code: B03AD04
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's. Rs. 60/-
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Bisleri-F Tablet M/s Sami Karachi.
	GMP status	Last Inspection report is of 10-2-2016 Firm has made improvement regarding as advised in GMP inspection but showed good intention to improve further.
	Remarks of the Evaluator.	Last inspection report does not fall within 1 year. Dossier was received through letter No.F.8-6/2013-Reg-V
	Decision of 273rd RB Meeting	Deferred for last GMP inspection report conducted within one year.
	Remarks of the Evaluator.	The firm has submitted latest GMP Inspection report dated 14.04.2022. A GMP certificate valid till 13.04.2024 is also submitted.
	Decision: Registration Board approved the case with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1717.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma (Pvt) Ltd. Lahore (DML No. 000492) Tablet Section (Antibiotic, General)
	Brand Name +Dosage Form + Strength	Thynor 5mg tablet
	Composition	Each tablet contains: Carbimazole……5mg
	Diary No. Date of R& I & fee	Dy. No.7960; 21-1-2011; Rs.8,000/- (21-1-2011); Rs.12,000/- (09-10-2015)
	Pharmacological Group	Anti-thyroid, Sulfur-containing imidazole derivatives.

		ATC Code: H03BB01
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	100's, Rs.98/-
	Approval status of product in Reference Regulatory Authorities.	Carbimazole 5mg Tablets (carbimazole) - PL 20620/0005 MHRA Approved.
	Me-too status	Carbil Tablet 5mg Reg. No. 038674 M/s Danas Pharmaceuticals (Pvt) Ltd. Islamabad.
	GMP status	Last Inspection report is of 10-2-2016 Firm has made improvement regarding as advised in GMP inspection but showed good intention to improve further.
	Remarks of the Evaluator.	Last inspection report does not fall within 1 year. Dossier was received through letter No.F.8-6/2013-Reg-V
	Decision of 273rd RB Meeting	Deferred for last GMP inspection report conducted within one year.
	Remarks of the Evaluator.	The firm has submitted latest GMP Inspection report dated 14.04.2022. A GMP certificate valid till 13.04.2024 is also submitted.
	Decision: Approved with BP Specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1718.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma (Pvt) Ltd. Lahore (DML No. 000492) Tablet Section (Antibiotic, General)
	Brand Name +Dosage Form + Strength	Moxiheim 400mg tablet
	Composition	Each film coated tablet contains: Moxifloxacin……400mg
	Diary No. Date of R& I & fee	Dy. No.7959; 21-1-2011; Rs.8,000/- (21-1-2011); Rs.12,000/- (09-10-2015)
	Pharmacological Group	Fluoroquinolones ATC Code: J01MA14
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14;s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Avelox 400 mg film-coated tablets by M/s Bayer plc, (MHRA approved)
	Me-too status	Metoxim 400mg Tablet by M/s Foray Pharmaceutical (Reg No:056083)
	GMP status	Last Inspection report is of 10-2-2016 Firm has made improvement regarding as advised in GMP inspection but showed good intention to improve further.
	Remarks of the Evaluator.	Last inspection report does not fall within 1 year. Pharmacological group is incorrect. Dossier was received through letter No.F.8-6/2013-Reg-V
	Decision of 273rd RB Meeting	Deferred for the following reasons: a) Submission of correct pharmacological group b) Deferred for last GMP inspection report conducted within one year.
	Remarks of the Evaluator.	The firm has submitted latest GMP Inspection report dated 14.04.2022. A GMP certificate valid till 13.04.2024 is also submitted. The firm has submitted corrected pharmacological group.
	Decision: Approved with USP Specifications. Firm shall submit revised label claim as per innovator product declaring the salt form of Moxifloxacin along with fee of Rs. 30,000/- for pre-approval change/correction in salt form of drug substance, as per notification No. 7-11/2012-B&A/DRAP dated 07.05.2021.	

1719.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma (Pvt) Ltd. Lahore (DML No. 000492) Capsule Section (General)
	Brand Name +Dosage Form + Strength	Azorin 250mg Capsule
	Composition	Each Capsule Contains: Azithromycin as dihydrate …250mg
	Diary No. Date of R& I & fee	Dy.No 13666 dated 07-03-2019 Rs.20,000/- (#0829121) Dated 06-03-2019
	Pharmacological Group	Macrolides. ATC Code: J01FA10
	Type of Form	Form-5
	Finished product Specification	Not mentioned in minutes of 295th meeting.
	Pack size & Demanded Price	10's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 250mg capsules hard (azithromycin dihydrate)- PL 14251/0073 MHRA Approved.
	Me-too status	Azomax 250mg Capsule Reg. No. 022200 M/s GSK Pakistan.
	GMP status	The firm has submitted latest GMP Inspection report dated 14.04.2022. A GMP certificate valid till 13.04.2024 is also submitted.
	Remarks of the Evaluator.	GMP NA
	Decision of 295th RB Meeting	**Deferred for updated status of GMP from QA & LT.**
	Remarks of the Evaluator.	The firm has submitted latest GMP Inspection report dated 14.04.2022. A GMP certificate valid till 13.04.2024 is also submitted.
	Decision: Approved with USP Specifications. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification o.F.7-11/2012B&A/DRAP dated 07-05-2021.	
1720.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma (Pvt) Ltd. Lahore (DML No. 000492) Oral Liquid Section (General)
	Brand Name +Dosage Form + Strength	Hilax Syrup
	Composition	Each 5ml Contains: Lactulose…3.335g
	Diary No. Date of R& I & fee	Dy.No. 13647: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Osmotically acting laxatives
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Duphalac (Lactulose 3.335 g/5 ml) clear, viscous liquid. MHRA approved
	Me-too status	Kohilac Syrup (Lactulose……3.35g). Reg. No. 55593
	GMP status	Required
	Remarks of the Evaluator.	**The quantity of API in applied and me-too product are different than that of international reference product.** • Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking • The firm was asked to provide source of lactulose. The firm submitted Fresenius Kabi, Austria.

		• The firm was asked to submit manufacturing outlines. The firm submitted that they will refill it.
	Previous decision (M-290)	Deferred revision of quantity of API from 3.35g to 3.335g along with submission of fee for revision of strength.
	Remarks of the Evaluator.	The firm revised the quantity of API from 3.35g to 3.335g (i.e., Each 5ml Contains: Lactulose…3.335g) along with submission of Rs. 7,500/- fee (Challan: 31931601612). • Revision of master formula is required
	Decision of 316th meeting	**Deferred for:** **• Revision of master formula.** **• Submission of differential fee of Rs. 22,500 for correction/pre-approval change in composition (correction/change of strength), as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.** **• Submission of valid GMP inspection report**
	Remarks of Evaluator	The firm has submitted; i. Revised Master formula. ii. Latest GMP Inspection report dated 14.04.2022. A GMP certificate valid till 13.04.2024 is also submitted. iii. Fee Rs. 22,500/- vide Slip No. 23381205908
	Decision: Approved.	
1721.	Name and address of manufacturer / Applicant	Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi (DML No.000105) Tablet Section (General)
	Brand Name +Dosage Form + Strength	ASAP 300mg Tablet
	Composition	Each enteric coated tablet contains: Acetylsalicylic acid (aspirin) ……..300mg
	Diary No. Date of R& I & fee	Dy No. 636, 21-02-2012. PKR 8000/- (15-02-2012) + PKR 12,000/- (13-12-2013)
	Pharmacological Group	Analgesic/Anti platelet
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	30's, as per PRC.
	Approval status of product in Reference Regulatory Authorities.	Aspirin 300mg Gastro-resistant Tablets MHRA Approved.
	Me-too status	Ascard-300 Tablets Reg. No. 016601 M/s Atco Laboratories Karachi.
	GMP status	Last Inspection conducted on 27.05.2022. Status is good.
	Remarks of the Evaluator.	Me-too status could not be confirmed as enteric coated tablet
	Decision of 273rd RB Meeting	Deferred for provision of generic / me-too status or else application on form-5D along with differential fee and stability study data.
	Remarks of the Evaluator.	The firm has provided 3 references of me-too products, i.e. Ascard 300mg Tablet Reg No. 016601, Loprin 300mg Tablet Reg. No. 013128 & Anaprin 300mg Tablet Reg. No. 015284
	Decision: Approved.	
1722.	Name and address of manufacturer / Applicant	M/s Mafins Pharma A-5 S.I.T.E Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Mifrox 550mg Tablet
	Composition	Each film coated tablet contains:

		Naproxen as sodium…550mg
	Diary No. Date of R& I & fee	Dy.No.834, 9-01-2017, Rs.20,000/-
	Pharmacological Group	Anti-inflammatory ATC Code: M01AE02
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Naproxen Sodium Eq 500mg Base (USFDA)
	Me-too status	Alligesic 550mg Tablet Reg. No. 061826 Each Tablet Contains; Naproxen Sodium 550mg M/s UDL Pharmaceuticals Karachi.
	GMP status	Last GMP Inspection dated 05-10-2017 with conclusive remarks of good cGMP compliance
	Remarks of the Evaluator.	The formulation is in reference in 500 mg strength.
	Decision of 279th RB Meeting	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting**
	Remarks of the Evaluator.	The firm has provided reference of Aleve Intense 550mg coated tablet approved by Medicine Evaluation Board (CBG MEG) Netherlands. The qualitative and quantitative composition given in summary of product characteristic is reproduced below; *"Tablet containing 550mg naproxen sodium.* *Aleve intense 550mg contains 50mg sodium per tablet"* The amount of sodium is also included in label claim of reference product, and amount of naproxen base can be calculated to be 500mg. The firm could not provide evidence of tablet containing 550mg Naproxen base as sodium salt.
	Decision: Approved with following label claim; **"Each film coated tablet contains;** **Naproxen sodium ……. 550mg** • **Registration letter shall be issued after submission of fee Rs. 30,000/- for change of label claim as per notification No. 7-11/2012-B&A/DRAP dated 07.05.2021.**	
1723.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Aksozine L Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloride…2.5mg
	Diary No. Date of R& I & fee	Dy No. 23076: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	30ml, 60ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	XYZAL (levocetirizine dihydrochloride) oral solution 0.5mg/ml. **USFDA** approved
	Me-too status	Lecetzi Syrup. Reg. No.79521
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature is placed on Form 5. • Filling and packing processes are missing in the manufacturing outlines.

	Decision of 291st RB Meeting	**Deferred for submission of manufacturing outlines**
	Remarks of the Evaluator.	The firm has provided the manufacturing outlines.
	Decision: Approved.	
1724.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Promazine Syrup 5mg/5ml
	Composition	Each 5ml contains: Promethazine HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 23078: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Phenothiazine derivatives
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml, 120ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Phenergan Elixir 5mg/5ml Oral Solution. **MHRA** approved
	Me-too status	Cofinol syrup. Reg No. 82278
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature are placed on Form 5. • The reference product is in the form of Exilir oral solution. • Filling and packing processes are missing in the manufacturing outlines.
	Decision of 291st RB Meeting	**Deferred for submission of manufacturing outlines**
	Remarks of the Evaluator.	The firm has provided the manufacturing outlines.
	Decision: Approved.	
1725.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Fexofin 30mg/5ml suspension
	Composition	Each 5ml contains: Fexofenadine HCl…30mg
	Diary No. Date of R& I & fee	Dy No. 23082: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TELFAST ORAL LIQUID fexofenadine hydrochloride 6 mg/mL oral suspension bottle. **TGA** approved
	Me-too status	Reliefex Suspension. Reg. No. 755802
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature is placed on Form 5. • Filling and packing process is missing in the manufacturing outlines.
	Decision of 291st RB Meeting	**Deferred for submission of manufacturing outlines**
	Remarks of the Evaluator.	The firm has provided the manufacturing outlines.
	Decision: Approved.	
1726.	Name and address of manufacturer / Applicant	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Swismox 400mg/250ml Injection
	Composition	Each Injection contains: Moxifloxacin(as hydrochloride)…400mg

	Diary No. Date of R& I & fee	Dy.No. 24095 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Moximed 400mg /250ml Infusion OF Medimarker's Hyderabad.
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of the Evaluator.	Section approval letter is required.
	Decision of 292nd RB Meeting	Registration Board in its 292nd deferred the case for the following: For approval of required manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Remarks of the Evaluator.	Applicant has submitted Evaluation form of inspection for renewal of DML conducted on 30-12-2014 showing evaluation of ampoule & vial injection general & panel recommended renewal of DML in stated inspection.
	Decision of 293rd meeting	Deferred for confirmation whether manufacturing facility of Ampoule & Vial Injection (General) is approved for "Small Volume Parenteral" or "Large Volume Parenteral". Likewise, for clarification regarding approval of required manufacturing facility & availability of equipment for applied drug product.
	Remarks of the Evaluator.	The firm has submitted that they have requested multiple times (letters dated 15.10.2020, 02.01.2020, 26.07.2021 and 02.11.2021) for processing of this case. The firm has submitted layout approval letter dated 18.06.2021 wherein LVP (General) section is mentioned. The firm currently does not have an LVP section and neither they had one at time of submission of application. The applied product is a Large Volume Parenteral(LVP).
	Decision: Deferred for submission of evidence of approval of required manufacturing facility for applied fill volume..	
1727.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt) Limited, 23- Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Asrin Plus Tablet
	Composition	Each bilayered tablet contains: Clopidogrel (as Clopidogrel Bisulphate)…….75mg Aspirin……..75mg
	Diary No. Date of R& I & fee	Dy. No. 2588, 20-06-2016; Rs.20,000/- (20-06-2016)
	Pharmacological Group	Inhibitor of ADP-mediated platelet aggregation and non-selective cyclo- oxygenase inhibitor
	Type of Form	Form -5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	As per SRO & as per SRO

	Approval status of product in Reference Regulatory Authorities.	Not provided
	Me-too status	Pidogrel-AP Tablet Reg. No. 038902 of M/s Highnoon Laboratories
	GMP status	Not Provided
	Remarks of the Evaluator.	• The latest GMP report is not provided by the firm. • The international availability of the applied formulation could not be confirmed. • Letter was issued on 2nd May, 2018 and the reminder has been issued on 10th July, 2018.
	Decision of 284th RB Meeting	**Registration Board deferred the case for further deliberation.**
	Remarks of the Evaluator.	• Firm has provided GMP certificate valid till 23.01.2022 issued on the basis of inspection conducted on 24.01.2022. • Firm has provided RRA reference of product registered in France. The product approved by ANSM France is CLOPIDOGREL/ACETYLSALICYLIC ACID MYLAN 75 mg/75 mg film-coated tablet. • The summary of product characteristics of Clopidogrel/Acetylsalicylic acid Zentiva available in EMA database were evaluated. The product is marketed in two strengths, 75mg/75mg and 75mg/100mg. Under heading of excipients, only single core is mentioned, indicating that tablet is not bilayer. Both strengths are film coated tablets with different colours. The firm has applied for a bilayer tablet.
	Decision: Deferred for evidence of availability of "Bi-layer tablet compression machine".	
1728.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt) Limited, 23- Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Zinki Syrup 20mg
	Composition	Each 5ml contains: - Zinc Sulphate Monohydrate eq. to elemental zinc …20mg
	Diary No. Date of R& I & fee	11-10-2013 vide Dy. No. 547 R&I Rs. 20,000/-
	Pharmacological Group	(Zinc/antidiarrhoeal) Other mineral supplements ATC Code: A12CB01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be verified. Monograph of Zinc Sulfate Oral Solution is present in USP.
	Me-too status	Zeesup 20mg/5ml Reg No. 069950 by M/s Global.
	GMP status	The firm is GMP compliant as per inspection dated 21-09-2015
	Remarks of the Evaluator.	The product is Under review for comments/ opinion from WHO
	Decision of 258th RB Meeting	Deferred for the comments/ opinion from WHO.
	Remarks of the Evaluator.	• Firm has provided GMP certificate valid till 23.01.2022 issued on the basis of inspection conducted on 24.01.2022. Zinc Sulfate is included in Who Model List of Essential Medicines for Children 22nd List (2021) under heading 17.5.2 Medicines for diarrhoea. It is mentioned as **solid**

		dosage form: 20mg, with comment that in acute diarrhea zinc sulfate should be used as an adjunct to oral rehydration salts. Dispersible The approval of product in RRA websites could not be verified but product monograph is available in USP as Zinc sulfate oral solution and its use is Who approved.
	Decision: Approved.	
1729.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt) Limited, 23- Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Nidazole Suspension
	Composition	Each 5ml contains: - Metronidazole as Benzoate……200mg Diloxanide Furoate…….250mg
	Diary No. Date of R& I & fee	11-10-2013 vide diary No. 545 R&I Rs.20,000.
	Pharmacological Group	AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES. ATC code: P01AB52
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be verified.
	Me-too status	Local. G-Zole 200mg/5ml & 250mg/5ml Suspension by M/s Olive Labs
	GMP status	Firm has provided GMP certificate valid till 23.01.2022 issued on the basis of inspection conducted on 24.01.2022.
	Remarks of the Evaluator.	Approval status in Reference countries is not provided.
	Decision of 258th RB Meeting	Deferred for confirmation of approval status by reference regulatory authorities.
	Remarks of the Evaluator.	The firm in their reply dated 01.11.2022 has stated that they are submitting SRA reference but they have submitted screenshots of Abbott Pakistan website. Authentic reference of SRA approval is still not provided.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1730.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt) Limited, 23- Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Nidazole DS Tablet
	Composition	Each tablet contains:- Metronidazole……..……400mg Diloxanide Furoate……...500mg
	Diary No. Date of R& I & fee	11-10-2013 vide diary No. 541 R&I Rs.20,000.
	Pharmacological Group	AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES. ATC code: P01AB52
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Local. G-Zole 400mg/500mg by M/s Olive
	GMP status	Firm has provided GMP certificate valid till 23.01.2022 issued on the basis of inspection conducted on 24.01.2022.

	Remarks of the Evaluator.	Approval status in reference countries is not provided.
	Decision of 258th RB Meeting	Deferred for confirmation of approval status by reference regulatory authorities.
	Remarks of the Evaluator.	The firm in their reply dated 01.11.2022 has stated that they are submitting SRA reference but they have submitted screenshots of Abbott Pakistan website. Authentic reference of SRA approval is still not provided.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1731.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt) Limited, 23- Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Bronil Syrup Sugar free
	Composition	Each 5 ml contains: Aminophylline……..…..32mg Diphenhydramine HCl…...8mg Ammonium Chloride…….30mg Menthol…….0.98mg
	Diary No. Date of R& I & fee	Dy. No. 17595; 10-10-2017; Rs.20,000/- (09-10-2017)
	Pharmacological Group	Anti-allergy and expectorant for relieve in productive cough.
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Registration No. 058021 Brand Name: Hydryllin Sugar Free Syrup Manufacturer Name: Searle Pakistan Limited
	GMP status	Firm has provided GMP certificate valid till 23.01.2022 issued on the basis of inspection conducted on 24.01.2022.
	Remarks of the Evaluator.	International availability could not be confirmed GMP inspection needed
	Decision of 312th RB Meeting	**Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**
	Remarks of the Evaluator.	The firm has still not provided authentic reference of RRA. The firm has stated vide letter No. SLL/DRAP-HR-000 dated 10.11.2022 that *"same formulation of Martin Dow Marker was registered in DRB 277th and they also mentioned Hydrylline Syrup as reference product for their product Cosome-E Syrup."* The minutes of 277th meeting were reviewed and the case of Cosome-E Syrup was of change of name of company from M/s Merk Marker to M/s Martin Dow.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1732.	Name and address of manufacturer / Applicant	M/s Wahabsons Pharmaceuticals, 4km Buner Road, Barikot, Swat
	Brand Name +Dosage Form + Strength	Zinkowab Syrup 20mg/5ml
	Composition	Each 5ml contains: Zinc Gluconate eq. to 2.8mg Elemental Zinc…..20mg
	Diary No. Date of R& I & fee	Dy. No. 3873, 24-05-2017; Rs.20,000/- (24-05-2017)
	Pharmacological Group	Zinc supplement
	Type of Form	Form 5

	Finished product Specification	Manufacturer's Specifications.
	Pack size & Demanded Price	60ml & Rs.62/-
	Approval status of product in Reference Regulatory Authorities.	Orazinc of M/s Mericon Industries (USFDA Approved)
	Me-too status	E-Zinc syrup of M/s Woodwards Pharmaceuticals
	GMP status	Last GMP inspection was conducted on 23-01-2017, and the report does not conclude GMP compliance.
	Remarks of the Evaluator.	The date of last inspection doesn't fall within one year. Letter has been issued on **26th April, 2018** and reminder has been issued on **10th July, 2018.**
	Decision of 284th RB Meeting	Registration Board deferred the case for further deliberation**. (M-284)**
	Remarks of the Evaluator.	Firm has submitted copy of GMP inspection report dated 25-10-2018, and the report does not have any conclusion and the recommendations include "Apart from aforementioned recommendations, the firm is further advised to □ Develop an independent quality assurance department and appoint an experienced assurance manager □ To improve water treatment system
	Decision of 286th RB Meeting	**Registration Board referred the case to QA&LT Division for updated GMP status of the firm.**
	Remarks of Evaluator	i. The evidence of approval in RRA could not be verified. ii. As per Dietary Reference Value (DRF) given by European Food Safety Authority the amount of zinc taken by an adult through normal diet is 8 to 14mg/day. The upper tolerable limit of zinc is 25mg/day. **iii.** The Tolerable upper Intake level of Zinc for adults as per health Canada is 40mg/day. iv. Based on above facts, it can be concluded that applied product may fall in category of Dietary Supplement.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1733.	Name and address of manufacturer / Applicant	M/s Wahabsons Pharmaceuticals, 4km Buner Road, Barikot, Swat (DML No. 000533) Dry Powder Suspension (General) Section.
	Brand Name +Dosage Form + Strength	Wamotid oral suspension
	Composition	Each 5ml contains: Famotidine……..10mg
	Diary No. Date of R& I & fee	Dy No. 237: 30-6-2016 PKR 20,000/-: 30-6-2016
	Pharmacological Group	Histamine H2 receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml amber coloured bottle: Rs 52/-
	Approval status of product in Reference Regulatory Authorities.	Internationally available as dry powder for suspension in the strength of 40 mg/ 5 ml.
	Me-too status	Peptiban suspension by Werrick
	GMP status	Could not be confirmed
	Remarks of the Evaluator.	• Evidence of approval in reference regulatory authorities could not be confirmed • GMP inspection report within last 1 year is required

	Decision of 284th RB Meeting	**Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**
	Remarks of the Evaluator.	The product approved by USFDA is FAMOTIDINE 40mg/5ml for suspension, Oral. Dry Powder Suspension (General) section approval letter vide No. F.3-5/99-Lic(Vol-I) dated 19.05.2022 is submitted. GMP inspection report dated 04.03.2022 is submitted
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
1734.	Name and address of manufacturer / Applicant	M/s Wahabsons Pharmaceuticals, 4km Buner Road, Barikot, Swat (DML No. 000533)
	Brand Name +Dosage Form + Strength	Weozine 2.5mg/ 5ml Syrup
	Composition	Each 5ml contains Levocetirizine dihydrochloride……2.5mg
	Diary No. Date of R& I & fee	Dy.No.2291; 22-02-2017; Rs.20,000/- (22-02-2017)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specifications.
	Pack size & Demanded Price	60ml; As Rs: 39/
	Approval status of product in Reference Regulatory Authorities.	Xyzal of (MHRA approved)
	Me-too status	Concidol-L Syrup of M/s Convell Laboratories
	GMP status	Last GMP inspection conducted on 15-02-2016, and the report concludes that firm is advised for purchase of stability chamber and done by firm as per their submitted compliance letter.
	Remarks of the Evaluator.	
	Decision of 279th RB Meeting	**Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. The Board also directed the firm to change the brand name.**
	Remarks of the Evaluator.	The firm has suggested name Rynor. Fee is not paid for change of brand name.
	Decision: Approved. Registration letter shall be issued after submission of latest GMP inspection report conducted within last three years and fee of Rs. 7,500/- for pre-approval change in brand name vide Notification No. 7-11/2012-B&A/DRAP dated 07.05.2021	

Agenda of Evaluator PEC-X

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

a. New section

I. M/s Winbrains Research Laboratories, Hattar. (New Section)

CLB in its 288th meeting held on 18th October, 2022 has considered and granted approval for the following two (02) additional sections of M/s Winbrains Research Laboratories, Hattar.

1. **Oral Liquid (General)-Veterinary**
2. **Oral Dry Powder (General)-Veterinary**

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

Section	No. of Products applied	No. of Molecules applied
Oral Liquid (General)-Veterinary	23	09
Oral Dry Powder (General)-Veterinary	12	07

Oral Liquid (General)-Veterinary

1735.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Floricol-C 23% Oral Solution
	Composition	Each 1000ml Contains: Florfenicol…230gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy. No 31441 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Fenicol-23 Oral Solution of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080731)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter.	
1736.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Floricol-C 25% Oral Solution
	Composition	Each 100ml Contains: Florfenicol…25gm Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy. No 31460 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Flocol Liquid of M/s D-Maarson Pharmaceuticals, Islamabad. (Reg. No. 074082)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022

	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter.	
1737.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Floricol-C 11% Oral Solution
	Composition	Each 100ml Contains: Florfenicol…11gm Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy. No 31467 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Flo Raft Oral Liquid of M/s Nawal Pharmaceuticals, Rawalpindi. (Reg. No. 078252)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter.	
1738.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Floricol 25% Oral Solution
	Composition	Each 100ml Contains: Florfenicol…25gm
	Diary No. Date of R& I & fee	Dy. No 31442 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Florfenicol Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075707)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1739.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Floricol 23% Oral Solution
	Composition	Each 100ml Contains: Florfenicol…23gm
	Diary No. Date of R& I & fee	Dy. No 31459 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications

	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Floral Plus Oral Liquid of M/s Nawal Pharmaceuticals, Taxila. (Reg. No. 074090)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1740.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Floricol 20% Oral Solution
	Composition	Each ml Contains: Florfenicol…200mg
	Diary No. Date of R& I & fee	Dy. No 31450 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Pri-Florecol 20 Oral Liquid of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 080928)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1741.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Enrof-C 20gm Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…20gm Colistin Sulphate…200,000 IU
	Diary No. Date of R& I & fee	Dy. No 31463 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Myrtleflox Oral Liquid of M/s Myrtle Pharma, Karachi. (Reg. No. 072608)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter.	
1742.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Enrof-C 25gm Oral Solution

	Composition	Each 100ml Contains: Enrofloxacin…25gm Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy. No 31455 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Vitaflox-C 25% Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 079276)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter.	
1743.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Enrof-C 200gm Oral Solution
	Composition	Each 1000ml Contains: Enrofloxacin…200gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy. No 31458 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	FLOXATIN 70 Oral Liquid of M/s Elegance Pharmaceuticals., Rawalpindi. (Reg. No. 078282)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter.	
1744.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Enrof-C 20gm/20 MIU Oral Solution
	Composition	Each 100ml Liquid Contains: Enrofloxacin…20gm Colistin Sulphate…20 MIU
	Diary No. Date of R& I & fee	Dy. No 31456 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Estin Liquid of M/S. Univet Pharmaceuticals, Rawalpindi. (Reg. No. 079133)

	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter with following label claim: **"Each 100ml Liquid Contains:** **EnrofloxacinHCl…20gm** **Colistin Sulphate…20 MIU"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product compositions as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
1745.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Enrof-C 10gm Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…52 MIU
	Diary No. Date of R& I & fee	Dy. No 31447 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Bioenrocolis Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 073916)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Liter.	
1746.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Telmicos Oral Solution
	Composition	Each ml contains: Tilmicosin as Phosphate…250mg
	Diary No. Date of R& I & fee	Dy. No 31440 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Telsin-P Oral Liquid of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 099297)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1747.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Trizine Oral Suspension

	Composition	Each 100ml Contains: Trimethoprim…8gm Sulfadiazine…40gm
	Diary No. Date of R& I & fee	Dy. No 31454 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	S.B. Sulfatrim Suspension of M/s S.B. Pharma Islamabad. (Reg. No. 020137)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1748.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Vitawin Oral Liquid
	Composition	Each Litre Contains: Vitamin E…150,000mg Selenium…2200mg Vitamin A…10,000,000 IU Vitamin B…16000mg Sorbitol…100000mg
	Diary No. Date of R& I & fee	Dy. No 31452 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Multi-vitamins
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2.5Liter: Decontrolled
	Me-too status	"Eselsorb Liquid of M/s Mallard Pharmaceuticals (Pvt) Ltd, Multan. (Reg. No. 112114)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Vitamin A from MIU to grams Vitamin A 10MIU= 3gram.
	Decision: Approved as per following composition: **"Each Liter contains: -** **Vitamin E…… 150000mg.** **Selenium (AS Sodium Selenite) 2200mg.** **Vitamin A ……. 10000000 I.U.** **Vitamin B2 …… 16000mg.** **Sorbital …….. 100000mg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product compsotion as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1749.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Lexyclo Oral Drench
	Composition	Each ml Contains: Levamisole HCl…15mg Cobalt Sulphate…1.67mg Oxyclozanide…30mg

		Sodium Selenite…0.50mg
	Diary No. Date of R& I & fee	Dy. No 31468 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Levoxbar-Plus Drench of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 075788)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1750.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Lexyclo-P Oral Drench
	Composition	Each 100ml Contains: Levamisole HCl…1.5gm Oxyclozanide…3.6gm Cobalt Sulphate…0.075gm Sodium Selenite…0.035gm
	Diary No. Date of R& I & fee	Dy. No 31451 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Nilzamine-Plus Suspension of M/s Jfrin Pharmaceuticals, Hub Lasbela, Baluchistan. (Reg. No. 048101)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1751.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Lexyclo-D Oral Drench
	Composition	Each 100ml Contains: Levamisole HCl…3gm Oxyclozanide…6gm Cobalt Sulphate…0.764gm Sodium Selenite…0.076gm
	Diary No. Date of R& I & fee	Dy. No 31439 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Vamiclosel-9 Liquid of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 093853)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022

	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1752.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Albend-CS 7.5% Oral Drench
	Composition	Each 100ml Contains: Albendazole…7.5gm Cobalt Sulphate…0.075gm Sodium Selenite…0.035gm
	Diary No. Date of R& I & fee	Dy.No 31464 dated 02-11-2022 Rs.30,000/- dated 02-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Albamont Oral Suspension of M/s Westmont Pharmaceutical Industries, Gujar khan (Reg. No. 048194)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1753.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Albend-CS 5% Oral Drench
	Composition	Each ml Contains: Albendazole…50mg Cobalt Sulphate…3.820mg Sodium Selenite…0.350mg
	Diary No. Date of R& I & fee	Dy. No 31462 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Ezole SC Drench of M/s Evergreen Pharmaceuticals, Lahore (Reg. No. 084845)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1754.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Sedox Oral Drench
	Composition	Each ml Contains: Oxyclozanide…62.5mg Oxfendazole…22.65mg Sodium Selenite…0.5mg Cobalt Sulphate…1.67mg
	Diary No. Date of R& I & fee	Dy. No 31465 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications

	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Oxfendaox Plus Oral Drench of M/s. Baariq Pharmaceuticals, Lahore (Reg. No. 075786)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1755.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Sedox D Oral Drench
	Composition	Each ml Contains: Oxyclozanide…62.50mg Oxfendazole…22.65mg Sodium Selenite…0.35mg Cobalt Sulphate…3.82mg
	Diary No. Date of R& I & fee	Dy.No 31466 dated 02-11-2022 Rs.30,000/- dated 02-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Galied Suspension of M/s. International Pharma Labs, Lahore (Reg. No. 063615)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1756.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Enrof 20% Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…20gm
	Diary No. Date of R& I & fee	Dy. No 31461 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Vety-Enrox Liquid of M/s Vety-Care Islamabad (Reg. No. 019940)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1757.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Enrof 25% Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…25gm
	Diary No. Date of R& I & fee	Dy. No 31469 dated 02-11-2022 Rs. 30,000/- dated 11-11-2022

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Bimro-25 Oral Liquid of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No.102244)
	GMP status	**Oral Liquid (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
Oral Dry Powder (General)-Veterinary		
1758.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Arthodex-W Oral W/S Powder
	Composition	Each 1000gm Contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy. No 31437 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Morenotyle Water Soluble Powder of M/s Moreno Iglisias Research Laboratories (Pvt) Ltd., Lahore. (Reg. No. 091892)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved.	
1759.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Arthodex Oral W/s Powder
	Composition	Each 1000gm Contains: Doxycycline HCl…250gm Tylosin Tartrate…200gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy. No 31444 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Bromodox Water Soluble Powder of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 063846)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1760.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athizem Plus Oral W/S Powder

	Composition	Each 1000gm Contains: Doxycycline HCl…400gm Tylosin Tartrate…200gm Colsitin Sulphate…1000MIU Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy. No 31436 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Monodox Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 087142)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Kg.	
1761.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athizem-T Oral W/S Powder
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colsitin Sulphate…400 MIU Bromhexine HCl…3gm
	Diary No. Date of R& I & fee	Dy. No 31445 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Bromodox-T Water Soluble Powder of M/s Attabak Pharma Islamabad (Reg. No. 049788)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Kg.	
1762.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athizem Oral W/S Powder
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colsitin Sulphate…480MIU Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy. No 31448 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Mucolytic

	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Emeria Shell Powder of M/s Inshaal Pharmaceutical Industries, Islamabad (Reg. No. 080515)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Kg.	
1763.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athizem-S Oral W/S Powder
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosin Tartrate…100gm Colsitin Sulphate…450MIU Bromhexine HCl…4gm
	Diary No. Date of R& I & fee	Dy. No 31449 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Doxyline Water Soluble Powder of M/s Inshaal Pharmaceutical Industries, Islamabad (Reg. No. 075776)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Provided conversion of Colistin Sulphate from MIU to grams Colistin Sulphate 19MIU= 1gram
	Decision: Approved upto pack size of 1Kg.	
1764.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Neomox 70% Oral W/S Powder
	Composition	Each 100gm Contains: Neomycin Sulphate…70gm
	Diary No. Date of R& I & fee	Dy. No 31470 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	Neomycin 70% Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No.075694)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1765.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.

	Brand Name +Dosage Form + Strength	Neomox 60% Oral W/S Powder
	Composition	Each 100gm Contains: Neomycin Sulphate…60gm
	Diary No. Date of R& I & fee	Dy. No 31443 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	Neocin-S Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 069625)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1766.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athycol-N Oral W/s Powder
	Composition	Each Gram Contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy. No 31446 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Neoxflor Oral Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 088638)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1767.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athoxy-P Oral W/s Powder
	Composition	Each 1000gm Contains: Oxytetracycline …300gm **Chloramphenicol…300gm** Neomycin Sulphate…150gm Salicylic Acid…50gm
	Diary No. Date of R& I & fee	Dy. No 31457 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic/Keratolytic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Ne-Oxy-Chlor Powder of M/s Farm Aid Group Rawalpindi (Reg. No. 033224)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were

		declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred till the decision of other applications of "Chloramphenicol" for which show cause has been issued.	
1768.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athbiowin Oral W/s Powder
	Composition	Each 100gm Contains: Calcium Fosfomycin…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm
	Diary No. Date of R& I & fee	Dy. No 31438 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Elefos-T Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi. (Reg. No. 105023)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1769.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Athfrowin Oral W/s Powder
	Composition	Each 1000gm Contains: Furosemide…20gm Sodium Chloride…35gm Magnesium Sulphate…35gm Manganese Sulphate…1gm Calcium Carbonate…45gm Potassium Chloride…4gm
	Diary No. Date of R& I & fee	Dy. No 31453 dated 02-11-2022 Rs. 30,000/- dated 02-11-2022
	Pharmacological Group	Flusher, Minerals
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	F-Flush Powder of M/s Attabak Pharmaceuticals Islamabad. (Reg. No. 053930)
	GMP status	**Oral Dry Powder (General) Veterinary section** granted vide letter No. F. 3-7/2007-Lic (Vol-I) dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	

II. M/s Athan pharmaceuticals, Hattar. (New Sections)

CLB in its 288th meeting held on 18th October, 2022 has considered and granted approval for the following three (03) additional sections of M/s Athan Pharmaceuticals, Hattar.

Oral Syrup (General)-Veterinary

Oral Powder (General)-Veterinary

Liquid Injectable-Vial (General)-Veterinary

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

Section	No. of Products applied	No. of Molecules applied
Oral Syrup (General)-Veterinary	**23**	**10**
Oral Powder (General)-Veterinary	**16**	**10**
Liquid Injectable-Vial (General)-Veterinary	**23**	**10**

Oral Syrup (General)-Veterinary 10 Molecules/ 23 Products		
1770.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Liflo Oral Suspension
	Composition	Each 1000ml Contains: Trimethoprim…80gm Sulphadiazine…400gm
	Diary No. Date of R& I & fee	Dy. No 33141 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1Liter, 2.5Liter, 25Liter: Decontrolled
	Me-too status	S.B.Sulfatrim Suspension of M/s S.B.Pharma Islamabad. (Reg. No. 020137)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of Liter.	
1771.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Albofyl D Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…55MIU Bromhexine HCl…0.5mg
	Diary No. Date of R& I & fee	Dy. No 33143 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 300ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

1772.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Albofyl Oral Solution
	Composition	Each 100ml Contains: Enrofloxacin…10gm Colistin Sulphate…50MIU Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy. No 33142 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 300ml, 500ml, 1000ml: Decontrolled
	Me-too status	Inter Flox Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078241)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved	
1773.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHCO D Oral Solution
	Composition	Each 100ml contains: Enrofloxacin...10g Colistin Sulphate…52MIU
	Diary No. Date of R& I & fee	Dy. No 33174 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Bioenrocolis Liquid of M/s Elegance Pharmaceutical, Rawalpindi. (Reg. No. 073916)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	
1774.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHCO Ex Oral Solution
	Composition	Each 1000ml contains: Enrofloxacin…200g Colistin Sulphate…500MIU
	Diary No. Date of R& I & fee	Dy. No 33175 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Floxatin 70 Oral Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 078282)

	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	
1775.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHCO M Oral Solution
	Composition	Each 100ml contains: Enrofloxacin…20gm Colistin sulphate…200,000IU
	Diary No. Date of R& I & fee	Dy. No 33176 dated 18-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Myrtleflox Oral Liquid of M/s Myrtle Pharma, Karachi. (Reg. No. 072608)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	
1776.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHCO T Oral Solution
	Composition	Each 100ml contains: Enrofloxacin…25g Colistin sulphate…50MIU
	Diary No. Date of R& I & fee	Dy. No 33177 dated 18-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Vitaflox-C 25% Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.079276)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	
1777.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHCO Z Oral Solution
	Composition	Each 100ml contains: Enrofloxacin…20gm Colistin Sulphate...20MIU
	Diary No. Date of R& I & fee	Dy. No 33178 dated 18-11-2022 Rs. 30,000/- dated 01-10-2022
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Henflox Oral Vet Liquid of M/s Hawk Bio Pharma (Pvt) Ltd., Islamabad. (Reg. No. 102093)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	
1778.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHFLOX 20% Oral Solution
	Composition	Each 100ml contains: Enrofloxacin...20g
	Diary No. Date of R& I & fee	Dy. No 33166 dated 18-11-2022 Rs. 30,000/- dated 01-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Vety-Enrox Liquid of M/s Vety-Care Islamabad (Reg. No. 019940)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1779.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHFLOX 25% Oral Solution
	Composition	Each 100ml contains: Enrofloxacin...25g
	Diary No. Date of R& I & fee	Dy. No 33167 dated 18-11-2022 Rs. 30,000/- dated 01-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Bimro-25 Oral Liquid of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No.102244)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1780.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	FENICOL-20 Oral Solution
	Composition	Each ml contains: Florfenicol…200mg
	Diary No. Date of R& I & fee	Dy. No 33169 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Pri-Florecol 20 Oral Liquid of M/s Prix Pharmaceutica (Pvt) Ltd, Lahore. (Reg. No. 080928)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1781.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	FENICOL-23 Oral Solution
	Composition	Each 100ml contains: Florfenicol...23g
	Diary No. Date of R& I & fee	Dy. No 33168 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Floral Plus Oral Liquid of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 074090)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1782.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	FENICOL-25 Oral Solution
	Composition	Each 100ml contains: Florfenicol...25g
	Diary No. Date of R& I & fee	Dy. No 33170 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Florfenicol Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075707)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1783.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	FENICOL-C 11% Oral Solution
	Composition	Each 100ml contains: Florfenicol...11g Colistin Sulphate…50MIU

	Diary No. Date of R& I & fee	Dy. No 33171 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Flo Raft Oral Liquid of M/s Nawal Pharmaceuticals, Taxila, Rawalpindi (Reg. No. 078252)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	
1784.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	FENICOL-C 23% Oral Solution
	Composition	Each 1000 mL contains: Florfenicol…230gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy. No 33172 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Fenicol-23 Oral Solution of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080731)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	
1785.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	FENICOL-C 25% Oral Solution
	Composition	Each 100ml contains: Florfenicol...25g Colistin Sulphate…50MIU
	Diary No. Date of R& I & fee	Dy. No 33173 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Flocol Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 074082)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Liter.	

1786.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	MICOS Oral Solution
	Composition	Each ml Contains: Tilmicosin as Phosphate…250mg
	Diary No. Date of R& I & fee	Dy. No 33165 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Telsin-P Oral Liquid of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad (Reg. No. 099297)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1787.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	SODOX D Oral Drench
	Composition	Each ml contains: Oxfendazole…22.65mg Oxyclozanide…62.50mg Cobalt Sulphate…3.82mg Sodium Selenite…0.35mg
	Diary No. Date of R& I & fee	Dy. No 33145 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Galied Suspension of M/s International Pharma Labs, Lahore. (Reg. No. 063615)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1788.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	SODOX Oral Drench
	Composition	Each ml Contains: Oxfendazole…22.65mg Oxyclozanide…62.5mg Cobalt Sulphate…1.67mg Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy. No 33144 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 450ml, 500ml, 750ml, 1000ml: Decontrolled

	Me-too status	Oxfendaox Plus Oral Drench of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 075786)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1789.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Leva Oral Drench
	Composition	Each ml Contains: Oxyclozanide…30mg Levamisole HCl…15mg Cobalt Sulphate…1.67mg Sodium Selenite…0.50mg
	Diary No. Date of R& I & fee	Dy. No 33146 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Levoxbar-Plus Drench of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 075788)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1790.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Leva D Oral Drench
	Composition	Each 100ml contains: Oxyclozanide…6gm Levamisole HCl…3gm Cobalt Sulphate…0.764gm Sodium Selenite...0.076gm
	Diary No. Date of R& I & fee	Dy. No 33147 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Vamiclosel-9 Liquid of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 093853)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1791.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Leva P Oral Drench
	Composition	Each 100ml contains: Oxyclozanide…3.6g Levamisole HCl…1.5g Cobalt Sulphate…0.075g

		Sodium selenite…0.035g
	Diary No. Date of R& I & fee	Dy. No 33148 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1Liter, 2.5Liter, 5Liter: Decontrolled
	Me-too status	Nilzamine-Plus Suspension of M/s Jfrin Pharmaceuticals, Hub Lasbela, Baluchistan. (Reg. No. 048101)`
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Liter.	
1792.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Vitavit Oral Liquid
	Composition	Each Litre Contains: Vitamin E…150000mg Selenium…2200mg Vitamin A…10000000 IU Vitamin B2…16000mg Sorbitol…100000mg
	Diary No. Date of R& I & fee	Dy. No 33140 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Multi-Vitamins
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2.5Liter: Decontrolled
	Me-too status	Megamune Liquid of M/s A&K Pharmaceuticals, Faisalabad. (Reg. No. 043562)
	GMP status	**Oral Syrup (General-Veterinary) section** granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Vitamin A 10MIU=3gm
	Decision: Approved as per following composition: **"Each Liter contains: -** **Vitamin E…… 150000mg.** **Selenium (AS Sodium Selenite) 2200mg.** **Vitamin A ……. 10000000 I.U.** **Vitamin B2 …… 16000mg.** **Sorbital …….. 100000mg"** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product compsotion as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
	Oral Powder (General)-Veterinary **10 Molecules/16 Products**	
1793.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHBIOTIC Oral W/S Powder
	Composition	Each 100gm contains: Calcium Fosfomycin…20gm Tylosin Tartrate…10gm Fructose…18gm Sodium Phosphate…15gm Magnesium Sulphate…10gm

	Diary No. Date of R& I & fee	Dy. No 33153 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic/Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Elefos-T Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi. (Reg. No. 105023)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1794.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHFROLYTE Oral W/S Powder
	Composition	Each 1000g contains: Furosemide…20g Sodium Chloride…35g Magnesium Sulphate…35g Manganese Sulphate…1g Calcium Carbonate…45g Potassium Chloride…4g
	Diary No. Date of R& I & fee	Dy. No 33150 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Flusher, Minerals
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	F-Flush Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 053930)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1795.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ARTHODOX D Oral W/S Powder
	Composition	Each 1000gm Contains: Tylosine Tartrate…200gm Doxycycline HCl…400gm Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy. No 33160 dated 18-11-2022 Rs. 30,000/- dated 18-11-2022
	Pharmacological Group	Antibitic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	Morenotyle Water Soluble Powder of M/s Moreno Iglisias Research Laboratories (Pvt) Ltd., Lahore. (Reg. No. 091892)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	

1796.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ARTHODOX Oral W/S Powder
	Composition	Each 1000gm Contains: Tylosine Tartrate…200gm Doxycycline HCl…250gm Bromhexine HCl…5000mg
	Diary No. Date of R& I & fee	Dy. No 33159 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibitic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Bromodox Water Soluble Powder of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063846)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1797.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATH-OXY Oral W/S Powder
	Composition	Each 100g Powder contains: Paracetamol…20g Potassium Carbonate…12.5g Sodium Carbonate…12.5g Vitamin E…12.5g Vitamin C…5g
	Diary No. Date of R& I & fee	Dy. No 33149 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Anti-inflammatory, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	50gm, 100gm, 200gm, 400gm, 500gm, 1000gm: Decontrolled
	Me-too status	Cemol Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 103909)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
1798.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHY-COL Oral Powder
	Composition	Each gram contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg
	Diary No. Date of R& I & fee	Dy. No 33152 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic/Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications

	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Neoxflor Oral Powder of M/s Baariq Pharmaceuticals, Lahore (Reg. No. 088638)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1799.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHZIM Oral W/S Powder
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosine Tartrate…100gm Colistin Sulphate…480 MIU Bromhexine HCl…5gm
	Diary No. Date of R& I & fee	Dy. No 33161 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Emeria Shell Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 080515)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Kg.	
1800.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHZIM PLUS Oral W/S Powder
	Composition	Each Kg contains Doxycycline HCl…400gm Tylosin Tartrate…200gm Colistin Sulphate…1000MIU Bromhexine HCl…10gm
	Diary No. Date of R& I & fee	Dy. No 33162 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator‘s specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 750gm, 1Kg: Decontrolled
	Me-too status	Monodox water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 087142)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved	
1801.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHZIM S Oral W/S Powder

	Composition	Each 1000gm contains: - Doxycycline HCl…200 gm Tylosin Tartrate…100 gm Colistin Sulphate…450 MIU Bromhexine HCl…4 gm
	Diary No. Date of R& I & fee	Dy. No 33164 dated 18-11-2022 Rs. 30,000/- dated 18-11-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Doxyline Water Soluble Powder of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad. (Reg. No. 075776)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Kg.	
1802.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHZIM T Oral W/S Powder
	Composition	Each 1000gm Contains: Doxycycline HCl…200gm Tylosine tartrate…100gm Colistin Sulphate…400 MIU Bromhexine HCl…3gm
	Diary No. Date of R& I & fee	Dy. No 33163 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic/Mucolytic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Bromodox-T Water Soluble Powder of M/s Attabak Pharma, Islamabad (Reg. No. 049788)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Kg.	
1803.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	NEOMIX 60% Oral W/S Powder
	Composition	Each 100gm contains: Neomycin Sulphate…60g
	Diary No. Date of R& I & fee	Dy. No 33154 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	Neocin-S Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 069625)

	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1804.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	NEOMIX 70% Oral W/S Powder
	Composition	Each 100gm Contains: Neomycin Sulphate…70gm
	Diary No. Date of R& I & fee	Dy. No 33151 dated 18-11-2022 Rs. 30,000/- dated 31-10-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 25Kg: Decontrolled
	Me-too status	Neomycin 70% Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075694)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1805.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	C-PAR Oral W/S Powder
	Composition	Each 100gm Contains: Neomycin Sulphate…250gm Colsitin Sulphate…300 MIU Oxytetracycline HCl…250gm
	Diary No. Date of R& I & fee	Dy. No 33155 dated 18-11-2022 Rs. 30,000/- dated 18-11-2022
	Pharmacological Group	Antibiotic/Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Neogence Powder of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 105022)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• The firm has submitted that Colistin sulphate 19MIU=1gm
	Decision: Approved upto pack size of 1Kg.	
1806.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	MUCOL Oral W/S Powder
	Composition	Each 100gm Contains: Colistin Sulphate…500,000,000IU
	Diary No. Date of R& I & fee	Dy. No 33157 dated 18-11-2022 Rs. 30,000/- dated 18-11-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled

	Me-too status	Colibak Forte Water Soluble Powder of M/s Attabak Pharma Islamabad (Reg. No. 049784)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1807.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	MUCOL B Oral W/S Powder
	Composition	Each 100gm Contains: Colistin Sulphate…480,000,000IU
	Diary No. Date of R& I & fee	Dy. No 33158 dated 18-11-2022 Rs. 30,000/- dated 18-11-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Coli D/S Powder of M/s Farm Aid Group Pakistan Haripur (Reg. No. 057105)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
1808.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ASPER Oral W/S Powder
	Composition	Each Gram Contains: Doxycycline HCl…500mg
	Diary No. Date of R& I & fee	Dy. No 33156 dated 18-11-2022 Rs. 30,000/- dated 18-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Me-too status	Fairo Dox 50 Powder of M/s Mallard Pharmaceutical (Pvt) Ltd. Multan. (Reg. No. 063782)
	GMP status	**Oral Powder (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved upto pack size of 1Kg.	
Liquid Injectable-Vial (General)-Veterinary 10 Molecules/ 23 Products		
1809.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ATHOCIN Injection
	Composition	Each ml contains: Oxytetracycline HCl…50mg
	Diary No. Date of R& I & fee	Dy. No 33137 dated 18-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibacterial/Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	Terrarok-M 50 Parenteral Solution of M/s Manhattan Pharma, Karachi. (Reg. No. 074043)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1810.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ENROX 20% Injection
	Composition	Each 100ml contains: Enrofloxacin…20g
	Diary No. Date of R& I & fee	Dy. No 33138 dated 18-11-2022 Rs. 30,000/- dated 08-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Eflocin 20% Injection of M/s Eros Pharmaceutical (Pvt) Ltd., Karachi. (Reg. No. 063766)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1811.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ENROX 20% Injection
	Composition	Each 100ml contains: Enrofloxacin…20g
	Diary No. Date of R& I & fee	Dy. No 33139 dated 18-11-2022 Rs. 30,000/- dated 08-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Eflocin 20% Injection of M/s Eros Pharmaceutical (Pvt) Ltd., Karachi. (Reg. No. 063766)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1812.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GENTA 100 Injection
	Composition	Each ml Contains: Gentamicin as Sulfate…100mg
	Diary No. Date of R& I & fee	Dy. No 33136 dated 18-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Genta-10 Super Injection of M/s Attabak Pharmaceuticals (Pvt) Ltd., Islamabad. (Reg. No. 075700)

	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1813.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GENTA 100 Injection
	Composition	Each ml Contains: Gentamicin as Sulfate…100mg
	Diary No. Date of R& I & fee	Dy. No 33440 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Genta-10 Super Injection of M/s Attabak Pharmaceuticals (Pvt) Ltd., Islamabad. (Reg. No. 075700)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1814.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GENTA 150 Injection
	Composition	Each ml Contains: Gentamicin as Sulfate…150mg
	Diary No. Date of R& I & fee	Dy. No 33441 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Genta-10 Super Injection of M/s Class Pharma Lahore (Reg. No. 018847)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1815.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GENTA 150 Injection
	Composition	Each ml Contains: Gentamicin as Sulfate…150mg
	Diary No. Date of R& I & fee	Dy. No 33442 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Genta-10 Super Injection of M/s Class Pharma Lahore (Reg. No. 018847)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	

	Decision: Approved	
1816.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GENTA 200 Injection
	Composition	Each ml Contains: Gentamicin as Sulfate…200mg
	Diary No. Date of R& I & fee	Dy. No 33443 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Elkogent Injection of M/s Elko Organisation Karachi (Reg. No. 021479)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1817.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GENTA 200 Injection
	Composition	Each ml Contains: Gentamicin as Sulfate…200mg
	Diary No. Date of R& I & fee	Dy. No 33444 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Elkogent Injection of M/s Elko Organisation Karachi (Reg. No. 021479)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1818.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GEN-TYLO 50 Injection
	Composition	Each ml Contains: Gentamicin Sulphate…50mg Tylosin Tartrate…100mg
	Diary No. Date of R& I & fee	Dy. No 33434 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Tylomit-G Injection of M/s Wimits Pharmaceuticals Lahore. (Reg. No. 088867)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	

1819.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GEN-TYLO 50 Injection
	Composition	Each ml Contains: Gentamicin Sulphate…50mg Tylosin Tartrate…100mg
	Diary No. Date of R& I & fee	Dy. No 33435 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Tylomit-G Injection of M/s Wimits Pharmaceuticals Lahore. (Reg. No. 078310)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1820.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GEN-TYLO 100 Injection
	Composition	Each ml Contains: Gentamicin Sulfate…100mg Tylosin Tartrate…50mg
	Diary No. Date of R& I & fee	Dy. No 33437 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	B.G. Genta Injection of M/s Biogen Pharma, Rawat. (Reg. No. 075624)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1821.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	GEN-TYLO 100 Injection
	Composition	Each ml Contains: Gentamicin Sulfate…100mg Tylosin Tartrate…50mg
	Diary No. Date of R& I & fee	Dy. No 33436 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	B.G. Genta Injection of M/s Biogen Pharma, Rawat. (Reg. No. 075624)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	

1822.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	TYLO Injection
	Composition	Each ml contains: Tylosin Tartrate Eq. to Tylosin…200mg
	Diary No. Date of R& I & fee	Dy. No 33432 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Tylin Injectable Solution of M/S Vet-Med Lahore. (Reg. No. 015460)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1823.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	TYLO Injection
	Composition	Each ml contains: Tylosin Tartrate Eq. to Tylosin…200mg
	Diary No. Date of R& I & fee	Dy. No 33433 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Tilosina Injectable Solution of M/S Punjnad Pharma (Pvt) Ltd., Lahore. (Reg. No. 099334)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1824.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	WORMECT 1% Injection
	Composition	Each 100ml contains: Ivermectin…1gm
	Diary No. Date of R& I & fee	Dy. No 33427 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Actimec Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 034595).
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1825.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.

	Brand Name +Dosage Form + Strength	WORMECT 1% Injection
	Composition	Each 100ml contains: Ivermectin…1gm
	Diary No. Date of R& I & fee	Dy. No 33428 dated 21-11-2022 Rs. 30,000/- dated 07-11-2022
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Actimec Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 034595).
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1826.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ORMECO Injection
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy. No 33429 dated 21-11-2022 Rs. 30,000/- dated 08-11-2022
	Pharmacological Group	Anthelmintic, Antiparasitic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Actimec Plus Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1827.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	ORMECO Injection
	Composition	Each ml Contains: Ivermectin…10mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy. No 33430 dated 21-11-2022 Rs. 30,000/- dated 08-11-2022
	Pharmacological Group	Anthelmintic, Antiparasitic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Actimec Plus Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 033251)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1828.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	VITOVIT High Injection

	Composition	Each ml contains: L-Arginine HCl...1.42mg L-Cysteine HCl...0.02mg Monosodium Glutamate...0.08mg L-Histidine HCl...0.02mg L-Isoleucine HCl...0.525mg L-Leucine...0.6mg L-Lysine HCl...0.525mg DL-Methionine...0.525mg L-Threonine...0.35mg L-Tryptophan...0.175mg L-Phenylaline...0.35mg L-Valine...0.525mg Thiamine HCl...0.1mg Riboflavin...0.05mg Pyridoxine HCl...0.1mg Nicotinamide...3mg Dextrose...50mg Calcium Chloride...2mg Potassium Chloride...2mg Magnesium sulphate...2mg Sodium acetate...7.5mg D-Pantothenol...0.1mg
	Diary No. Date of R& I & fee	Dy. No 33426 dated 21-11-2022 Rs. 30,000/- dated 08-11-2022
	Pharmacological Group	Vitamins, Amino acids, Minerals
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	**250ml:** Decontrolled
	Me-too status	Enersel Injection of M/s Selmore, Lahore. (Reg. No. 112275)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• Approval of Liquid Injectable- Vial(General)-Veterinary **(Large Volume Parenteral)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **Evidence of availability of manufacturing facility for applied fill volume.** • **Evidence of availability of testing facility for applied product along with analytical procedure.**	
1829.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	THORVIT Injection
	Composition	Each ml contains: Vitamin A…500000IU Vitamin D3…75000IU Vitamin E…50mg
	Diary No. Date of R& I & fee	Dy. No 33431 dated 21-11-2022 Rs. 30,000/- dated 08-11-2022
	Pharmacological Group	Multi Vitamins
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Duravit AD3E Injection (Vet) of M/s Mylab (Pvt) Ltd.

		Khanqah Sharif, Bahawalpur (Reg. No. 074018)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	• Vitamin A conversion: 10,000IU = 3mg • Vitamin D3 conversion: 1000 IU= 0.025mg
	Decision: Approved	
1830.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	TYLOPET Injection
	Composition	Each ml contains: Tylosin Tartrate…50mg Colistin sulphate…10mg Streptomycin as sulphate…100mg
	Diary No. Date of R& I & fee	Dy. No 33438 dated 21-11-2022 Rs. 30,000/- dated 14-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ceticin Injection (50ml) of M/S Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101518)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1831.	Name and address of manufacturer / Applicant	M/s Athan Pharmaceuticals, Plot 84/1, Block B, Phase V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	TYLOPET Injection
	Composition	Each ml contains: Tylosin Tartrate…50mg Colistin sulphate…10mg Streptomycin as sulphate…100mg
	Diary No. Date of R& I & fee	Dy. No 33439 dated 21-11-2022 Rs. 30,000/- dated 14-11-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	PRO CRD Injection (100ml) of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 087132)
	GMP status	**Liquid Injectable-Vial (General)-Veterinary** section granted vide letter No. F. 1-16/2013-Lic. dated 08-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	

III: M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, 20-Km Ferozepur Road, Lahore. Central Licensing Board in its 287th meeting held on 24th June, 2022 has considered and approved the following additional section of firm M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, 20-Km Ferozepur Road, Lahore. Accordingly, the Secretary CLB has issued letter for grant of additional section dated 04th July, 2022.

In 321st meeting below mentioned products have been considered on priority against new sections as detailed below:

Sr. No.	Section	Previously considered applications

		Molecules	Products
01	**Oral powder penicillin section**	**07**	**10**

Now following applications of the firm have been received and are presented below for consideration, against the available balance for priority consideration.

Oral powder penicillin section
02 Molecules/ 02 Products

1832.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, 20-Km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	PPS-Plus Powder
	Composition	Each 1000gm Contains: Procaine Penicillin (Procaine Benzylpenicillin) …12gm Streptomycin Sulphate…36gm Zinc Bacitracin…52gm Colistin Sulphate…60 MIU
	Diary No. Date of R& I & fee	Dy. No 33423 dated 21-11-2022 Rs. 30,000/- dated 17-11-2022
	Pharmacological Group	Antibacterial/Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1Kg, 5Kg, 25Kg, 50Kg: Decontrolled
	Me-too status	BPS-Plus Powder of M/S Baariq Pharmaceuticals, Lahore. (Reg. No.087171)
	GMP status	**Oral powder (Penicillin) section** granted vide letter No. F. 1-31/2010-Lic (Vol-I) dated 04-07-2022
	Remarks of the Evaluator [X]	The firm was asked to provide conversion of Colistin Sulphate from MIU to grams. In this regard it has been submitted, *That the observation related to API **Colistin Sulphate** and its conversion from MIU to Grams, is variable, consequent upon the **COA of Active Raw material, and its Assay**, which always vary from batch to batch, so this API need to be ascertained its weight vis-à-vis its assay.* *There is no hard and fast rule to ascertain its weight, before the authentication of assay, so this objection may not be considered as mandatory, considering the manufacturing of the product and its assay of the batch.*
	Decision: Approved with pack size of 1Kg.	
1833.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, 20-Km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	GPS-100 Powder
	Composition	Each 1000gm Contains: Procaine Penicillin (Procaine Benzylpenicillin) …12gm Streptomycin Sulphate…36gm Zinc Bacitracin 10%…52gm
	Diary No. Date of R& I & fee	Dy. No 33424 dated 21-11-2022 Rs. 30,000/- dated 17-11-2022
	Pharmacological Group	Antibacterial/Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1Kg, 5Kg, 25Kg, 50Kg: Decontrolled
	Me-too status	Probac Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088099)
	GMP status	**Oral powder (Penicillin) section** granted vide letter No. F. 1-31/2010-Lic (Vol-I) dated 04-07-2022

	Remarks of the Evaluator [X]	
	Decision: Approved with pack size of 1Kg.	

IV: M/s Ras Pharmaceuticals Pvt Ltd., 25-Km Lahore Road, Multan. (New Section)

CLB in its 288th meeting held on 18th October, 2022 has considered and granted the approval for following two (02) additional sections of M/s Ras Pharmaceuticals Pvt Ltd., Multan.

Topical spray Section-Veterinary

Injectable (Hormones) Section-Veterinary

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

Section	No. of Products applied	No. of Molecules applied
Topical spray Section-Veterinary	**03**	**03**
Injectable (Hormones) Section-Veterinary	**13**	**06**

Topical spray (General) -Veterinary Section
03 Molecules/03 products

1834.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Ras Oxygent Spray
	Composition	Each Gram Contains: Oxytetracycline HCl…40mg Gentian Violet…4mg
	Diary No. Date of R& I & fee	Dy.No 31773 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml: N/A
	Me-too status	Oxygaurad-G Spray of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 079108)
	GMP status	**Topical spray (General)-Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1835.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Chlorit Spray
	Composition	Each ml Contains: Chlortetracycline HCl…15.2mg
	Diary No. Date of R& I & fee	Dy.No 31776 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml: N/A
	Me-too status	Biochlor Aerosol Spray of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 088094)
	GMP status	**Topical spray (General)-Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved	
1836.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan

	Brand Name +Dosage Form + Strength	OxyFly Plus Spray
	Composition	Each Gram Contains: Oxytetracycline HCl…5mg Hydrocortisone…1.6mg
	Diary No. Date of R& I & fee	Dy.No 31775 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml, 250ml: N/A
	Me-too status	Cortisel Spray of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071079)
	GMP status	**Topical spray (General)-Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	• Initially, the firm has applied for Oxytetracycline HCl…5mg, Hydrocortisone…1.6mg **per gram;** however, the referred generic product contains same quantities of APIs, per ml instead of grams, as applied. Now, the firm has submitted following formulation as per reference product. **Each ml contains:** **Oxytetracycline HCl…5mg** **Hydrocortisone…1.6mg** • The firm has submitted fee Rs. 7500 for revision of label claim vide slip No. 35261075316 **Shortcomings:** ➢ Balance fee Rs. 22500/- for revision of label claim.
	Decision: Approved with following formulation: **Each ml contains:** **Oxytetracycline HCl…5mg** **Hydrocortisone…1.6mg** **Registration letter shall be issued after submission of differential fee of Rs.22,500/- for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
Injectable (Hormones) -Veterinary Section **06 Molecules/ 13 products** **Registration Board deliberated that the approved section is "Injectable (Hormone)" and applied products include both non-steroidal Hormone and Steroidal Hormone formulations. Hence as informed by the firm they want to retain only "Non-Steroidal Hormone Formlations" and the Board accordingly considered and decided as under:**		
1837.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Fertigrow Injection 2.5ml
	Composition	Each ml Contains: Buserelin Acetate 0.0042mg Eq. to Buserelin…0.004mg
	Diary No. Date of R& I & fee	Dy.No 31767 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	2.5ml: N/A
	Me-too status	Bosol Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 083245)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved with change of brand name..	

1838.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Fertigrow Injection 5ml
	Composition	Each ml Contains: Buserelin Acetate 0.0042mg Eq. to Buserelin…0.004mg
	Diary No. Date of R& I & fee	Dy.No 31766 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	5ml: N/A
	Me-too status	Bosol Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 101516)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved with change of brand name. Firm shall submit fee of Rs. 7,500/- fro pre-approval change of brand name as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1839.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Recilin Injection 2ml
	Composition	Each ml contains: Lecirelin----------25mcg
	Diary No. Date of R& I & fee	Dy.No 31765 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	2ml: N/A
	Me-too status	Serilin Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 071092)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved.	
1840.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Recilin Injection 10ml
	Composition	Each ml contains: Lecirelin----------25mcg
	Diary No. Date of R& I & fee	Dy.No 31764 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	10ml: N/A
	Me-too status	Serilin Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 071092)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved.	

1841.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Ovicin-20 Injection 100 ml
	Composition	Each 100ml contains: Oxytocin (Synthetic)----------2000 I.U
	Diary No. Date of R& I & fee	Dy.No 31763 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: N/A
	Me-too status	Oxytovet Injection of M/s International Pharma Labs., Lahore (Reg. No. 074756)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Deferred for approval of required manufacturing facility of "Injectable (Steroidal hormone)- Veterinary Section" by CLB.	
1842.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Ovicin Injection 50 ml
	Composition	Each ml contains: Oxytocin (Synthetic)----------10 I.U
	Diary No. Date of R& I & fee	Dy.No 31760 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: N/A
	Me-too status	Oxytofas Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 073982)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Deferred for approval of required manufacturing facility of "Injectable (Steroidal hormone)- Veterinary Section" by CLB.	
1843.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Ovicin Injection 100 ml
	Composition	Each ml contains: Oxytocin (Synthetic)----------10 I.U
	Diary No. Date of R& I & fee	Dy.No 31761 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml: N/A
	Me-too status	Oxytofas Injection of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 073982)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Deferred for approval of required manufacturing facility of "Injectable (Steroidal hormone)- Veterinary Section" by CLB.	

1844.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Ovicin Injection 250 ml
	Composition	Each ml contains: Oxytocin (Synthetic)----------10 I.U
	Diary No. Date of R& I & fee	Dy.No 31762 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	**250ml**: N/A
	Me-too status	Oxytovetz Injection of M/s Vetz Pharmaceuticals (Private) Limited, Kotri Sindh. (Reg. No. 111470)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	The firm has submitted panel inspection report dated 01-06-2022 and 03-08-2022 for grant of additional section **confirming two filling machines were installed in this area. One vial filling machine automatic two nozzle with automatic sealing and capping while other machine was single nozzle.**
	Decision: Deferred for approval of required manufacturing facility of "Injectable (Steroidal hormone)- Veterinary Section" by CLB.	
1845.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Raspro Injection 10ml
	Composition	Each ml contains: Progesterone----------25 mg
	Diary No. Date of R& I & fee	Dy.No 31771 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml: N/A
	Me-too status	Pregtone Injection 10ml of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058711)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	Requirement for steroidal manufacturing facility since the **applied molecule is steroidal hormone.**
	Decision: Deferred for approval of required manufacturing facility of "Injectable (Steroidal hormone)- Veterinary Section" by CLB.	
1846.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Raspro Injection 50ml
	Composition	Each ml contains: Progesterone----------25 mg
	Diary No. Date of R& I & fee	Dy.No 31774 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: N/A
	Me-too status	Progestone Injection 50ml of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 063695)

	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	Requirement for steroidal manufacturing facility since the **applied molecule is steroidal hormone.**
	Decision: Deferred for approval of required manufacturing facility of "Injectable (Steroidal hormone)- Veterinary Section" by CLB.	
1847.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Cloproras Injection 10ml
	Composition	Each ml contains: Cloprostenol Sodium----------263mcg (Equivalent to Cloprostenol ……250 mcg)
	Diary No. Date of R& I & fee	Dy.No 31759 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	10ml: N/A
	Me-too status	Prostenol Injection 10ml of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 029611)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved.	
1848.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Cloproras Injection 2ml
	Composition	Each ml contains: Cloprostenol Sodium----------263mcg (Equivalent to Cloprostenol ……250 mcg)
	Diary No. Date of R& I & fee	Dy.No 31772 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	2ml: N/A
	Me-too status	Prostenol Injection 2ml of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 029611)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved.	
1849.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Prostiras Injection 5ml
	Composition	Each ml contains: Dinoprost (as trometamol)----------5 mg
	Diary No. Date of R& I & fee	Dy.No 31770 dated 04-11-2022 Rs.30,000/- dated 31-10-2022
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	5ml: N/A

	Me-too status	Dprost Liquid Injection 5ml of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 088647)
	GMP status	**Injectable (Hormones) -Veterinary Section** granted vide letter No. F. 1-46/2010-Lic (Vol-I) dated 11-11-2022
	Remarks of the Evaluator [X]	
	Decision: Approved.	

Case No.02: Registration applications for local manufacturing of (veterinary) drugs
a. New cases

1850.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Trisal Gold Suspension
	Composition	Each ml contains: Triclabendazole…….50mg Levamisole HCl……37.5mg Cobalt Sulphate…....1.67mg Sodium Selenite…….0.35mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 62 dated 10-09-2013 Rs.20,000/- dated 10-09-2013 (**Duplicate fee challan attached**)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	**Innovator's specifications**
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Trizole SC Suspension of M/s Star Laboratories (Pvt) Limited, Lahore. (Reg. No. 063602)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator [X]	**Oral Liquid (Veterinary) section** granted vide letter No. F. 1-30/2001-Lic (M-212) dated 14-06-2008
	Decision: Approved with Innovator's Specifications. Firm shall submit fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. Moreover, fee shall be verified as per procedure adopted by Registration Board in its 285th meeting.	
1851.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Moxidek Injection
	Composition	Each vial contains: Moxidectin…….1% w/v
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 63 dated 10-09-2013 Rs.20,000/- dated 10-09-2013 (**Duplicate fee challan attached**)
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Cydectin 1% Injectable **50ml** of M/s Rhone Poluene (Pvt) Ltd Lahore (Reg. No. 019034) **could not be confirmed in the applied fill volume**
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator [X]	**Veterinary Liquid injection (General) section** granted vide letter No. F. 1-30/2001-Lic (M-212) dated 14-06-2008

		Shortcomings: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the **same fill volume as applied** alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the same fill volume as applied alongwith registration number, brand name and name of firm.	
1852.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Furasid Injection
	Composition	Each 100ml contains: Furosemide……5gm
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 360 dated 08-10-2015 Rs.20,000/- dated 08-10-2015 (**Duplicate fee challan attached**)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml: Decontrolled
	Me-too status	Dinavet 5% Injection **(10ml, 20ml)** of M/s Leads Pharma (Pvt) Ltd Islamabad. (Reg. No. 057056) .
	GMP status	Not submitted
	Remarks of the Evaluator [x]	• Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved with Innovator's Specifications. Registration letter shall be issued after submission of following: • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **GMP inspection report conducted within the period of last three years** • **Choice of fill volume of 10ml or 20ml.** • **Fee verification as per procedure adopted by Registration Board in its 285th meeting.**	
1853.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Akacin 200-PVP injection
	Composition	Each ml contains: Oxytetracycline HCl……200mg
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP**

		Dy.No 346 dated 08-10-2015 Rs.20,000/- dated 08-10-2015 (**Duplicate fee challan attached**)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml: Decontrolled
	Me-too status	Oxy Shell 20% Injection **(100ml)** of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 080511)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier and submit accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) in the applied fill volume/pack size alongwith registration number, brand name and name of firm..
	Decision: Approved with Innovator's Specifications and with fill volume of 100ml. **Registration letter shall be issued after submission of following:** • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **GMP inspection report conducted within the period of last three years** • **Fee verification as per procedure adopted by registration Board in its 285th meeting.**	
1854.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Tribin Drench
	Composition	Each 100ml contains: Triclabendazole……5gm
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 362 dated 08-10-2015 Rs.20,000/- dated 08-10-2015 (**Duplicate fee challan attached**)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	100ml, 450ml, 500ml, 1Liter; Decontrolled
	Me-too status	Focinex Suspension of M/s Delux Chemical Industries, Karachi (Reg. No. 026585)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit

		panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.
	Decision: Approved with Innovator's Specifications. **Registration letter shall be issued after submission of following:** • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **GMP inspection report conducted within the period of last three years** • **Fee verification as per procedure adopted by registration Board in its 285th meeting**	
1855.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Fendacare Drench
	Composition	Each 100ml contains: Fenbendazole……..2.5gm
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 361 dated 08-10-2015 Rs.20,000/- dated 08-10-2015 (**Duplicate fee challan attached**)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	100ml, 450ml, 500ml, 1Liter; Decontrolled
	Me-too status	Avi-Fen Liquid of M/s Avicenna Laboratories (Pvt) Ltd., Sheikhupura. (Reg. No. 063656)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.
	Decision: Approved with Innovator's Specifications. **Registration letter shall be issued after submission of following:** • **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.** • **GMP inspection report conducted within the period of last three years** • **Fee verification as per procedure adopted by registration Board in its 285th meeting**	
1856.	Name and address of manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name +Dosage Form + Strength	Milko-Plus Granules
	Composition	Each kg Contains: Calcium…….155 grams Phosphorus……135 grams Magnesium……..…55 grams Sodium…….45 grams

		Iron……..…1 grams Zinc……3 grams Manganese…..…2 grams Copper……0.6 grams Cobalt……..0.01 grams Iodine……0.04 grams
	Diary No. Date of R& I & fee	**Duplicate dossier submitted which was confirmed from R&I section, DRAP** Dy.No 42766 dated 14-12-2018 Rs.20,000/- dated 14-12-2018 (**Duplicate fee challan attached**)
	Pharmacological Group	Immunological, electrolyte
	Type of Form	Form 5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	1Kg Jar, 5Kg bag, 10Kg bag, 25Kg bag; Decontrolled
	Me-too status	L.S. Minerals Powder of M/s Nawan Labs Karachi. (Reg. No. 021306)
	GMP status	Not submitted
	Remarks of the Evaluator [X]	• Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.
	Decision: Deferred for evidence of testing facility and completion of salt form.	

Agenda of Evaluator PEC-XI

Case No. 01: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Titlis Pharma, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore
The Central Licensing Board in its 285th meeting held on 17th & 18th March, 2022 has considered and approved the grant of following sections of **M/s Titlis Pharma, Plot No. 528-A, Sundar Industrial Estate, Raiwand Road, Lahore** under Drug Manufacturing License No. 000779 (Formulation) vide approval letter No. F. 1-11/2009-Lic (Vol-I) dated 10th May, 2022.

S No.	Section
	Tablet Section II (General) **New**
	Dry Powder Suspension Section. **New**
	Dry Powder Sachet Section (General). **New**

Following applications have been submitted for registration by the firm.

1857.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A , Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A , Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20726 dated 22/07/2022
	Details of fee submitted	PKR 30,000/-: dated 10/06/2022 (Slip#136469119630)
	The proposed proprietary name / brand name	**Respiklar 125mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Clarithromycin ……. 125mg/5ml
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Klaricid Paediatric Suspension 125mg/5ml MHRA Approved
	For generic drugs (me-too status)	Claritek Granules for Oral Suspension 125mg/5mg by M/s Getz Pharma (Reg#09846)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CTM0510, CTM0511, CTM0513)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Claritek 125mg/5ml Dry Powder Suspension by M/s Getz Pharma by performing quality tests (pH, Assay, Dissolution, weight/ml and weight variation) and results are within specifications
	Analytical method validation/verification of product	Firm has submitted method verification studies including specify, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Private) Limited, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	CTM0678		
Description of Pack (Container closure system)	Amber colored glass bottle sealed with aluminium PP cap printed with 'Titlis Pharma' packed in cardboard carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RP-01	RP-02	RP-03
Batch Size	100 Bottle	100 Bottle	100 Bottle
Manufacturing Date	Dec-2021	Dec-2021	Dec-2021
Date of Initiation	12-12-2021	12-12-2021	12-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted;
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022. The firm has also submitted receiving of request applied for GMP Inspection dated 22nd December 2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted;
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted;
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted;

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while	The firm submitted that the title of our company has been changed in 279th meeting of Central Licensing Board, and the new approved title is "Titlis Pharma (Private) Limited". The change of title approval letter from Central Licensing Board

	name mentioned on DML is M/s Titlis Pharma., Clarification is required	in the name of "Titlis Pharma (Private) Limited" is submitted.
1.5.2	• Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall be clearly mentioned	The firm has submitted the Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit as: Each 5 ml contains: Clarithromycin…… 125mg
2.3.R	• In executed BMR percentage of clarithromycin (granules) is written as 28.33 % while in module 3 section 3.2.P.1 percentage of clarithromycin (granules) is written as 27.5%, clarification is required	The firm submitted that the specification of Clarithromycin taste masked pellets being used is 27.5% (Limit is 24.75% to 30.25%) as per manufacturer's COA; and COA of Vision Pharma is submitted., We M/S Titlis Pharma performed testing of API (Clarithromycin taste masked pellets 27.5%; Batch # CTM0678) and results of assay was 28.33% which was well within the specified limit (COA of API from Titlis Pharma is submitted). Thus the specification of Clarithromycin granules being used is 27.5% and in executed BMR the percentage of Clarithromycin granules was mentioned as 28.33% which was as per our QC results
3.2.S.4	• Copies of the specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Copies of the specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator/comparator product including the tests recommended USP monograph (deliverable volume, loss on drying). • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?	• The firm submitted that we have performed all the tests as per USP monograph including deliverable volume & loss on drying in pharmaceutical equivalence study; and revised Pharmaceutical Equivalence Study Reports are submitted • The firm submitted that Pharmaceutical Equivalence Study has been established against the innovator product 'Klaricid 125mg/5ml Dry Powder suspension' of Abbot Laboratories and against 'Claritek 125mg/5ml Dry Powder suspension' of Getz Pharma by performing quality tests as per USP; and results are within specifications and comparable with both Klaricid and Claritek dry powder suspension. Pharmaceutical Equivalence Study Reports against Klaricid is submitted.
3.2.P.5	• Justification is required for not including test for deliverable volume in specifications as recommended by USP • Justification is required since chromatographic conditions mentioned in analytical procedure (injection volume 20ul instead of 50ul, column length 250 mm instead of 15cm) is different from that recommended by USP • Justification is required for using 100rpm in dissolution studies instead of 50rpm as recommended by USFDA dissolution database	• The firm submitted that we have revised the specification and included the test for deliverable volume in finished product specification; as per USP. The firm has also submitted revised specification and analytical method • The firm submitted that sample and standard were analyzed under same chromatographic conditions (including the same injection volume) and found that the results were closely comparable. • The firm submitted that USP <621> states that injection volume can be adjusted as it is consistent with acceptable precision. • The firm submitted we have performed analytical method validation in which we did extensive testing taking different concentrations under heading of Limit of Detection, Limit of Quantification, Linearity, Accuracy and Recovery. Results of above said validation parameters complied with the Relative Standard Deviation limits. ***However, firm have submitted analytical method verification studies and not method validation studies.***

Justification is required for using 100rpm in dissolution studies instead of 50rpm as recommended by USFDA dissolution database;

The firm submitted that we have performed the dissolution testing at 50rpm for our product Respiklar 125mg/5ml Dry Powder Suspension' and innovator's 'Klaricid 125mg/5ml Dry Powder Suspension', and the results are as follows:

Dissolution data table:
Dissolution Study at 50 RPM

Limit: NLT 75 % in 45 minutes at 50 RPM

Respiklar Dry Powder Suspension 125mg/5ml
Batch No: RP-01
Dissolution Results:
Minimum %= 87.38% Maximum %= 96.24% Average %= 92.01%

Batch No: RP-02
Dissolution Results:
Minimum %= 86.33% Maximum %= 98.45% Average %= 92.52%

Batch No: RP-03
Dissolution Results:
Minimum %= 87.63% Maximum %= 96.00% Average %= 92.13%

Klaricid Dry Powder Suspension 125mg/5ml
Batch No: 412897XV
Dissolution Results:
Minimum %= 89.86% Maximum %= 100.25% Average %= 96.30%

Dissolution Study at 100 RPM
Limit: NLT 75 % in 45 minutes at 100 RPM

Respiklar Dry Powder Suspension 125mg/5ml
Batch No: RP-01
Dissolution Results:
Minimum %= 88.78% Maximum %= 101.47% Average %= 94.95%

Batch No: RP-02
Dissolution Results:
Minimum %= 91.01% Maximum %= 99.77% Average %= 95.29%

Batch No: RP-03
Dissolution Results:
Minimum %= 93.46% Maximum %= 101.56% Average %= 96.06%

Klaricid Dry Powder Suspension 125mg/5ml
Batch No: 412897XV
Dissolution Results:
Minimum %= 85.17% Maximum %= 97.21% Average %= 88.35%

The data shows there is no impact of change of rpm as the results are more than 80% within 45 minutes.
We further undertake in future, we will perform all the testing at 50rpm

3.2.P.6	Clarification is required since the submitted COA of reference / working standard is from M/s Nexchem Pharmaceutical Co., Ltd China and it follow enterprise standard specifications while source of API is M/s Vision Pharma and the product monograph is available in USP

Firm's Response: Firm submitted a comparison table of tests for USP specifications and specifications followed by Working standard of M/s Nexchem Pharmaceutical.

TEST PERFORMED	SPECIFICATION USP	Working standard Nexchem Pharmaceutical; RESULTS
Description	White to almost white crystalline powder	Complies
Solubility	Practically insoluble in water, soluble in methyl chloride, and in acetone, Slightly soluble in phosphate buffer at pH values of 2 to 5.	Complies
Identification	The FTIR spectrum of sample must concordant with spectrum of reference standard.	Complies
pH	7.5 – 10.0	8.5
Water Contents	Not More Than 2.0% w/w	0.87% w/w

Sulphated Ash	NMT 0.2%	0.02%
Heavy Metals	--------	0.02%
Residual solvents (Ethanol)	--------	0.002%
Related Substances 1. Any individual impurity 2. NMT 4 such impurity 3. Total Impurities	1. NMT 1.0% 2. NMT 0.4% 3. NMT 3.5%	1. 0.18% 2. Complies 3. 0.75%
Assay By HPLC	96.0% - 102% w/w (Anhydrous)	98.0%w/w DS

*The working standard from Nexchem Pharmaceuticals Co; the results are well within USP specs.
Now currently we are using Working standard of USP Specs from Vision Pharma (COA Copy attached)
We undertake that in future we will always use the Working Standard of USP Specs.

3.2.P.8	• Tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> should be performed for finished product • In use stability study of reconstitution suspension shall be submitted • Submit documents for procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Firm has submitted antimicrobial preservative content and efficacy of preservative for finished product • Firm has submitted in use stability study of reconstitution suspension • Firm has submitted invoice No#60008 dated 07-12.2021 from M/s Vision Pharma in name of M/s Titlis Pharma (Pvt) Ltd for purchase of 5kg Clarithromycin Taste Masked Micro Pellets 27.5% Batche No. CTM0678. • Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers at accelerated conditions only and not at real time conditions

Decision: Approved with following label claim:
Each 5 ml contains:
Clarithromycin…… 125mg

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

Registration letter will be issued upon submission of following:

- **Pharmaceutivcal Equivalence & CDP studies performed against the innovator product.**
- **IQ, OQ and PQ reports of the HPLC equipped with oven having capacity to maintain column temperature at 50°C.**
- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

1858	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A , Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A , Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20725 dated 22/07/2022
	Details of fee submitted	PKR 30,000/-: dated 10/06/2022

		(Slip#76875447030)
	The proposed proprietary name / brand name	Respiklar 250mg/5ml Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Clarithromycin ……. 250mg/5ml
	Pharmaceutical form of applied drug	Dry powder suspension
	Pharmacotherapeutic Group of (API)	Macrolide Antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Klaricid Paediatric Suspension 250mg/5ml MHRA Approved
	For generic drugs (me-too status)	Claritek Granules for Oral Suspension 250mg/5ml by M/s Getz Pharma (Reg#061347)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CTM0510, CTM0511, CTM0513)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Claritek 250mg/5ml Dry Powder Suspension by M/s Getz Pharma by performing quality tests (pH, Assay, Dissolution, weight/ml and weight variation) and results are within specifications
	Analytical method validation/verification of product	Firm has submitted method verification studies including specify, accuracy, precision.
STABILITY STUDY DATA		

Manufacturer of API	Vision Pharmaceuticals (Private) Limited, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan		
API Lot No.	CTM0678		
Description of Pack (Container closure system)	Amber colored glass bottle sealed with aluminium PP cap printed with 'Titlis Pharma' packed in cardboard carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RP-04	RP-05	RP-06
Batch Size	100 Bottle	100 Bottle	100 Bottle
Manufacturing Date	Dec-2021	Dec-2021	Dec-2021
Date of Initiation	12-12-2021	12-12-2021	12-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Submitted;
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022. The firm has also submitted receiving of request applied for GMP Inspection dated 22nd December 2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not Submitted;
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted;
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted;

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	The firm submitted that the title of our company has been changed in 279th meeting of Central Licensing Board, and the new approved title is "Titlis Pharma (Private) Limited". The change of title approval letter from Central Licensing Board in the name of "Titlis Pharma (Private) Limited" is submitted.
1.5.2	• Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit shall be clearly mentioned	The firm has submitted the Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit as: Each 5 ml contains: Clarithromycin…… 250mg
3.2.S.4	• Copies of the specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product	• Copies of the specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is submitted.

	manufacturer for drug substance(s) shall be submitted.	
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator/comparator product including the tests recommended USP monograph (deliverable volume, loss on drying). • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?	• The firm submitted that we have performed all the tests as per USP monograph including deliverable volume & loss on drying in pharmaceutical equivalence study; and revised Pharmaceutical Equivalence Study Reports are submitted • The firm submitted that Pharmaceutical Equivalence Study has been established against the innovator product 'Klaricid 250mg/5ml Dry Powder suspension' of Abbot Laboratories and against 'Claritek 250mg/5ml Dry Powder suspension' of Getz Pharma by performing quality tests as per USP; and results are within specifications and comparable with both Klaricid and Claritek dry powder suspension. Pharmaceutical Equivalence Study Reports against Klaricid is submitted.
3.2.P.5	• Justification is required for not including test for deliverable volume in specifications as recommended by USP • Justification is required since chromatographic conditions mentioned in analytical procedure (injection volume 20ul instead of 50ul, column length 250 mm instead of 15cm) is different from that recommended by USP • Justification is required for using 100rpm in dissolution studies instead of 50rpm as recommended by USFDA dissolution database	• The firm submitted that we have revised the specification and included the test for deliverable volume in finished product specification; as per USP. The firm has also submitted revised specification and analytical method • The firm submitted that sample and standard were analyzed under same chromatographic conditions (including the same injection volume) and found that the results were closely comparable. • The firm submitted that USP <621> states that injection volume can be adjusted as it is consistent with acceptable precision. • The firm submitted that we have performed analytical method validation in which we did extensive testing taking different concentrations under heading of Limit of Detection, Limit of Quantification, Linearity, Accuracy and Recovery. Results of above said validation parameters complied with the Relative Standard Deviation limits. ***However, firm have submitted analytical method verification studies and not method validation studies***

Justification is required for using 100rpm in dissolution studies instead of 50rpm as recommended by USFDA dissolution database;

The firm submitted that we have performed the dissolution testing at 50rpm for our product Respiklar 250mg/5ml Dry Powder Suspension' and innovator's 'Klaricid 250mg/5ml Dry Powder Suspension', and the results are as follows:

Dissolution data table:
Dissolution Study at 100 RPM
Limit: NLT 75 % in 45 minutes at 100 RPM

Respiklar Dry Powder Suspension 250mg/5ml
Batch No: RP-04
Dissolution Results:
Minimum %= 90.72% Maximum %= 95.17% Average %= 92.95%

Batch No: RP-05
Dissolution Results:
Minimum %= 89.47% Maximum %= 97.81% Average %= 94.77%

Batch No: RP-06
Dissolution Results:
Minimum %= 91.93% Maximum %= 93.37% Average %= 92.71%

Klaricid Dry Powder Suspension 250mg/5ml
Batch No: 452376XV
Dissolution Results:
Minimum %= 96.93% Maximum %= 105.03% Average %= 100.24%

Dissolution Study at 50 RPM
Limit: NLT 75 % in 45 minutes at 50 RPM

Respiklar Dry Powder Suspension 250mg/5ml
Batch No: RP-04
Dissolution Results:
Minimum %= 82.21% Maximum %= 87.28% Average %= 86.12%

Batch No: RP-05
Dissolution Results:
Minimum %= 87.58% Maximum %= 102.09% Average %= 90.70%

Batch No: RP-06
Dissolution Results:
Minimum %= 88.26% Maximum %= 89.90% Average %= 89.05%

Klaricid Dry Powder Suspension 250mg/5ml
Batch No: 452376XV
Dissolution Results:
Minimum %= 93.42% Maximum %= 98.83% Average %= 96.29%

The data shows there is no impact of change of rpm as the results are more than 80% within 45 minutes.
We further undertake in future, we will perform all the testing at 50rpm.

3.2.P.6	Clarification is required since the submitted COA of reference / working standard is from M/s Nexchem Pharmaceutical Co., Ltd China and it follow enterprise standard specifications while source of API is M/s Vision Pharma and the product monograph is available in USP

Firm's Response: Firm submitted a comparison table of tests for USP specifications and specifications followed by Working standard of Nexchem Pharmaceutical.

TEST PERFORMED	**SPECIFICATION USP**	**Working standard Nexchem Pharmaceutical; RESULTS**
Description	White to almost white crystalline powder	Complies
Solubility	Practically insoluble in water, soluble in methyl chloride, and in acetone, Slightly soluble in phosphate buffer at pH values of 2 to 5.	Complies
Identification	The FTIR spectrum of sample must concordant with spectrum of reference standard.	Complies
pH	7.5 – 10.0	8.5
Water Contents	Not More Than 2.0% w/w	0.87% w/w
Sulphated Ash	NMT 0.2%	0.02%
Heavy Metals	--------	0.02%
Residual solvents (Ethanol)	--------	0.002%
Related Substances 4. Any individual impurity 5. NMT 4 such impurity 6. Total Impurities	 4. NMT 1.0% 5. NMT 0.4% 6. NMT 3.5%	 4. 0.18% 5. Complies 6. 0.75%
Assay By HPLC	96.0% - 102% w/w (Anhydrous)	98.0%w/w DS

*The working standard from Nexchem Pharmaceuticals Co; the results are well within USP specs.
Now currently we are using Working standard of USP Specs from Vision Pharma (COA Copy attached)
We undertake that in future we will always use the Working Standard of USP Specs.

3.2.P.8	• Tests for antimicrobial preservative content and efficacy of preservative as recommended by USP chapter <51> should be performed for finished product • In use stability study of reconstitution suspension shall be submitted • Submit documents for procurement of API	• Firm has submitted antimicrobial preservative content and efficacy of preservative for finished product • Firm has submitted in use stability study of reconstitution suspension • Firm has submitted invoice No#60008 dated 07-12-2021 from M/s Vision Pharma in name of M/s Titlis Pharma (Pvt) Ltd for purchase of 5kg Clarithromycin Taste Masked Micro Pellets 27.5% Batche No. CTM0678.

	• Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers at accelerated conditions only and not at real time conditions

Decision: Approved with following label claim:
Each 5 ml contains:
Clarithromycin…… 250mg

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

Registration letter will be issued upon submission of following

- **Pharmaceutivcal Equivalence & CDP studies performed against the innovator product.**
- **IQ, OQ and PQ reports of the HPLC equipped with oven having capacity to maintain column temperature at 50°C.**
- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

1859.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12953 dated 27/05/2022
	Details of fee submitted	PKR 30,000/-: dated 28/03/2022 (Slip#13298631296)
	The proposed proprietary name / brand name	Dametit Tablet 5mg/850mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Dapagliflozin propanediol monohydrate….5mg Metformin Hydrochloride……..850mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antidiabetics, Biguanides Antidiabetics, SGLT2 Inhibitors
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO (5mg/850mg;; 5mg/1000mg) film coated tablet EMA Approved
	For generic drugs (me-too status)	Daplozmet 5mg/850mg Tablets by M/s Highnoon Laboratories (Reg#96588)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	**Dapagliflozin propanediol monohydrate:**

		Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Dapagliflozin propanediol monohydrate** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin Hydrochloride** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Daplozmet 5/850mg Tablet of M/s Highnoon Laboratories Ltd by performing quality tests (disintegration, weight variation, Dissolution and Assay). CDP has been performed against the same brand that is Daplozmet 5/850mg Tablet of M/s Highnoon Laboratories Ltd in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.
STABILITY STUDY DATA		
Manufacturer of API	**Dapagliflozin propanediol monohydrate:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China.	

	<u>Metformin HCL</u>: Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155		
API Lot No.	**Dapagliflozin Propanediol Monohydrate**: L-DG-20210418-D01-DG06-01 **Metformin Hydrochloride:** MEF/10041416		
Description of Pack (Container closure system)	ALU-ALU blister packed in cardboard unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DP-07	DP-08	DP-09
Batch Size	700 tab	700 tab	700 tab
Manufacturing Date	Oct-2021	Oct-2021	Oct-2021
Date of Initiation	18-12-2021	18-12-2021	18-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**<u>Dapagliflozin propanediol monohydrate:</u>** The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Dapagliflozin propanediol monohydrate by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Metformin HCl: The firm has submitted GMP certificate for Aarti Drugs Limited (Unit-II) India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 19-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	The firm submitted that the title of our company has been changed in 279th meeting of Central Licensing Board, and the new approved title is "Titlis Pharma (Private) Limited". The change of title approval letter from Central Licensing

<table>
<tr><td></td><td></td><td>Board in the name of “Titlis Pharma (Private) Limited” is submitted.</td></tr>
<tr><td>1.5.2</td><td>Correct the label claim considering the salt factor in case of dapagliflozin propanediol monohydrate as per reference formulation along with submission of applicable fee</td><td>We would like to submit that our label claim was with same interpretation as that of innovator product.
However, we have revised our label claim as per innovator and the revised label claim is;
Each film coated Tablet contains:
Dapagliflozin propanediol monohydrate eq. to Dapagliflozin ……...5mg
Metformin Hydrochloride…..850mg</td></tr>
<tr><td>1.6.5</td><td>Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for dapagliflozin propanediol monohydrate issued by relevant regulatory authority of country of origin</td><td>The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Dapagliflozin propanediol monohydrate by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024</td></tr>
<tr><td>3.2.S.4</td><td>• Justification is required for not including test for quantification of propylene glycol content in dapagliflozin drug substance specification by drug substance manufacturer & drug product manufacturer as recommended by innovator product review document
• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Dapagliflozin by Drug Product manufacturer is required.
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Dapagliflozin and Metformin HCl shall be submitted.
• Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method.
• Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.</td><td>• The firm submitted that innovator product did not use propylene glycol in its formulation and we also did not use Propylene Glycol in our formulation. Hence test for quantification of propylene glycol content in Dapagliflozin drug Substance specification by drug substance manufacturer & drug product manufacturer is not included. However, it is to submit that test for quantification of propylene glycol content in dapagliflozin drug substance specification by drug substance manufacturer & drug product was asked and not in drug product specification
• Copies of the specifications and analytical procedures used for routine testing of the Drug substance Dapagliflozin by Drug product manufacturer is submitted.
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Dapagliflozin and Metformin HCl is submitted.
• The firm submitted that previously, we were performing the assay of Metformin HCL on titrimetric method. However, we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph. The testing and COA of most recent batch of metformin HCL (Batch no; MEF/12051645) as per USP Method is submitted.
• The firm submitted that previously, we were performing the analysis of Metformin HCL by BP method. However, we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph and test for appearance of solution and sulphated ash is not mentioned in USP monograph.
• The testing METHOD and COA of most recent batch of metformin HCL as per USP Method is submitted.</td></tr>
<tr><td>3.2.P.2</td><td>• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>XIGDUO tablet</th></tr>
<tr><td>Dapagliflozin Propanediol Monohydrate Metformin HCl</td><td>Dapagliflozin as dapagliflozin propanediol monohydrate Metformin HCl</td></tr>
<tr><td>Lactose</td><td>Hydroxypropyl cellulose</td></tr>
</table></td><td>• The firm submitted that as per literature review and study of Hand Book for Pharmaceutical Excipients, it is notable that all the excipients used in our formulation are inert, and are compatible with active pharmaceutical ingredient of Dametit tablet 5mg/850mg. Moreover, their safety and compatibility have also been established as no harsh / adverse effect has been observed in our stability studies.
• The firm further stated that we have also performed Drug Excipients Compatibility studies. However, no compatibility studies is submitted
• The firm submitted that we have performed Pharmaceutical Equivalance study of Dametit 5mg/850mg Tablet against the reference product Daplozmet 5mg/850mg Tablet Manufactured by Highnoon Laboratories Limited. As the</td></tr>
</table>

	<table><tr><td>Avecil PH 102</td><td>Microcrystalline cellulose</td></tr><tr><td>Starch</td><td>Magnesium Stearate</td></tr><tr><td>PVP K30</td><td>Sodium starch glycolate</td></tr><tr><td>Aerosil 200</td><td></td></tr><tr><td>Ac-di-sol</td><td></td></tr><tr><td>Magnesium stearate</td><td></td></tr><tr><td>Purified water</td><td></td></tr></table> • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?	innovator product is not registered in Pakistan therefore, Pharmaceutical Equivalance study of the Dametit 5mg/850mg Table was performed against the reference product Daplozmet 5mg/850mg Tablet Manufactured by Highnoon Laboratories Limited, which is available in the market.
3.2.P.5	• Justification is required for not including test for identification test for dapagliflozin and metformin, uniformity of dosage units dapagliflozin (content uniformity, HPLC) and metformin (mass variation) in finished product specification as recommended by innovator product review document. • Analytical procedure for disintegration test is not given in the submitted analytical method	• The firm submitted that we have revised the specification and included the test for identification test for Dapagliflozin and metformin, uniformity of dosage units dapagliflozin (content uniformity) and metformin (mass variation) in finished product specification as recommended by innovator product review document. Revised method and COA is submitted • The firm has submitted analytical procedure for disintegration test in analytical method.
3.2.P.8	• Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as provided in finished product specifications • Submit documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• The firm submitted that our dissolution specification are NLT 80% in 30 minutes as provided in finished product specifications but by typographic error it was written NLT 75% in 45 minutes in stability study summary sheets. Revised stability study summary sheets is submitted • Firm has submitted copy of invoice for procurement of API. **Dapagliflozin Propanediol Monohydrate:** Firm has submitted copy of invoice No. HN210630-J dated 30-06-2021 for import of 0.150kg of Dapagliflozin Propanediol Monohydrate (Batch# L-DG-20210418-D01-DG06-01) in name of M/s Titlis Pharma (Pvt.) Limited attested by AD (I&E) DRAP Lahore dated 12-08-2021 **Metformin HCl:** Firm has submitted copy of invoice No. EXP/321/20-21 dated 18-05-2020 for import of 1000kg of Metformin HCl (Batch# MEF/10041416) in name of M/s Titlis Pharma (Pvt.) Limited attested by AD (I&E) DRAP Lahore dated 25-06-2020. • Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers at accelerated conditions only and not at real time conditions

Decision: Approved with innovator's specifications and following label claim:
Each film coated Tablet contains:
Dapagliflozin propanediol monohydrate eq. to Dapagliflozin ……...5mg
Metformin Hydrochloride……. …..850mg

- **Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt factor of the drug substance) and correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Firm shall perform test for quantification of propylene glycol content in dapagliflozin drug substance by drug substance manufacturer as recommended by innovator product review document before issuance of registration letter**
- **Firm shall submit Compatibility studies of the Drug Substance(s) with excipients as the qualitative composition of the formulation is not similar to innovator / reference product before issuance of registration letter**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1860	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11024 dated 30/04/2022
	Details of fee submitted	PKR 30,000/-: dated 28/03/2022 (Slip#881347060)
	The proposed proprietary name / brand name	Dametit Tablet 5mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Dapagliflozin……..….5mg Metformin Hydrochloride……..1000mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antidiabetics, Biguanides Antidiabetics, SGLT2 Inhibitors
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO (5mg/850mg;; 5mg/1000mg) film coated tablet EMA Approved
	For generic drugs (me-too status)	Daplozmet 5mg/1000mg Tablets by M/s Highnoon Laboratories (Reg#96589)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	**Dapagliflozin Propanediol Monohydrate:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Dapagliflozin Propanediol Monohydrate** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin Hydrochloride** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Not submitted
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.

STABILITY STUDY DATA

Manufacturer of API	**Dapagliflozin Propanediol Monohydrate:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCL:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155		
API Lot No.	**Dapagliflozin Propanediol Monohydrate**: L-DG-20210418-D01-DG06-01 **Metformin Hydrochloride:** MEF/10041416		
Description of Pack (Container closure system)	ALU-ALU blister packed in cardboard unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	DP-10	DP-11	DP-12
Batch Size	700 tab	700 tab	700 tab
Manufacturing Date	Oct-2021	Oct-2021	Oct-2021
Date of Initiation	18-12-2021	18-12-2021	18-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**<u>Dapagliflozin Propanediol Monohydrate:</u>** The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Dapagliflozin propanediol monohydrate by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Metformin HCl: The firm has submitted GMP certificate for Aarti Drugs Limited (Unit-II) India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 19-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	The firm submitted that the title of our company has been changed in 279th meeting of Central Licensing Board, and the new approved title is "Titlis Pharma (Private) Limited". The change of title approval letter from Central Licensing Board in the name of "Titlis Pharma (Private) Limited" is submitted.
1.5.2	• Revise the label claim mentioning the correct salt and hydrated form of dapagliflozin as per reference formulation along with submission of applicable fee.	The firm have revised the label claim mentioning the correct salt and hydrated form of dapagliflozin as per innovator and the revised label claim is; Each film coated Tablet contains: Dapagliflozin propanediol monohydrate eq. to Dapagliflozin ……...5mg Metformin Hydrochloride…..1000mg
1.6.5	Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for dapagliflozin propanediol monohydrate issued by relevant regulatory authority of country of origin	The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Dapagliflozin propanediol monohydrate by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024
3.2.S.4	• Justification is required for not including test for quantification of propylene glycol content in dapagliflozin drug substance specification by drug substance manufacturer & drug product manufacturer as recommended by innovator product review document • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Dapagliflozin by Drug Product manufacturer is required.	• The firm submitted that innovator product did not use propylene glycol in its formulation and we also did not use Propylene Glycol in our formulation. Hence test for quantification of propylene glycol content in Dapagliflozin drug Substance specification by drug substance manufacturer & drug product manufacturer is not included. ***However, it is to submit that test for quantification of propylene glycol content in dapagliflozin drug substance specification by drug substance manufacturer & drug product was asked and not in drug product specification***

<table>
<tr>
<td></td>
<td>
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Dapagliflozin and Metformin HCl shall be submitted.
• Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method.
• Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.
</td>
<td>
• Copies of the specifications and analytical procedures used for routine testing of the Drug substance Dapagliflozin by Drug product manufacturer is submitted.
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) Dapagliflozin and Metformin HCl is submitted.
• The firm submitted that previously, we were performing the assay of Metformin HCL on titrimetric method. However, we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph. The testing and COA of most recent batch of metformin HCL (Batch no; MEF/12051645) as per USP Method is submitted.
• The firm submitted that previously, we were performing the analysis of Metformin HCL by BP method. However, we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph and test for appearance of solution and sulphated ash is not mentioned in USP monograph.
• The testing METHOD and COA of most recent batch of metformin HCL as per USP Method is submitted.
</td>
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<tr>
<td>3.2.P.2</td>
<td>
• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>XIGDUO tablet</th></tr>
<tr><td>Dapagliflozin Propanediol Monohydrate Metformin HCl</td><td>Dapagliflozin as dapagliflozin propanediol monohydrate Metformin HCl</td></tr>
<tr><td>Lactose</td><td>Hydroxypropyl cellulose</td></tr>
<tr><td>Avecil PH 102</td><td>Microcrystalline cellulose</td></tr>
<tr><td>Starch</td><td>Magnesium Stearate</td></tr>
<tr><td>PVP K30</td><td>Sodium starch glycolate</td></tr>
<tr><td>Aerosil 200</td><td></td></tr>
<tr><td>Ac-di-sol</td><td></td></tr>
<tr><td>Magnesium stearate</td><td></td></tr>
<tr><td>Purified water</td><td></td></tr>
</table>
• Pharmaceutical equivalence and CDP of the applied product has not been submitted.
• Only protocol for CDP is submitted
</td>
<td>
• The firm submitted that as per literature review and study of Hand Book for Pharmaceutical Excipients, it is notable that all the excipients used in our formulation are inert, and are compatible with active pharmaceutical ingredient of Dametit tablet 5mg/1000mg. Moreover, their safety and compatibility have also been established as no harsh / adverse effect has been observed in our stability studies.
• The firm further stated that we have also performed Drug Excipients Compatibility studies. ***However, no compatibility studies is submitted.***
• The firm have submitted pharmaceutical equivalence and CDP of the applied product.
Pharmaceutical Equivalence have been established against Daplozmet 5/1000mg Tablet of M/s Highnoon Laboratories Ltd by performing quality tests (disintegration, weight variation, Dissolution and Assay).
CDP has been performed against the same brand that is Daplozmet 5/1000mg Tablet of M/s Highnoon Laboratories Ltd in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
</td>
</tr>
<tr>
<td>3.2.P.5</td>
<td>
• Justification is required for not including test for identification test for dapagliflozin and metformin, uniformity of dosage units dapagliflozin (content uniformity) and metformin (mass variation) in finished product specification as recommended by innovator product review document.
• Analytical procedure for disintegration test is not given in the submitted analytical method
</td>
<td>
• The firm submitted that we have revised the specification and included the test for identification test for Dapagliflozin and metformin, uniformity of dosage units dapagliflozin (content uniformity) and metformin (mass variation) in finished product specification as recommended by innovator product review document. Revised method and COA is submitted
• The firm has submitted analytical procedure for disintegration test in analytical method.
</td>
</tr>
</table>

3.2.P.8	• Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as provided in finished product specifications • Submit documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• The firm submitted that our dissolution specification is NLT 80% in 30 minutes as provided in finished product specifications but by typographic error it was written NLT 75% in 45 minutes in stability study summary sheets. Revised stability study summary sheets is submitted • Firm has submitted copy of invoice for procurement of API. **Dapagliflozin Propanediol Monohydrate:** Firm has submitted copy of invoice No. HN210630-J dated 30-06-2021 for import of 0.150kg of Dapagliflozin Propanediol Monohydrate (Batch# L-DG-20210418-D01-DG06-01) in name of M/s Titlis Pharma (Pvt.) Limited attested by AD (I&E) DRAP Lahore dated 12-08-2021 **Metformin HCl:** Firm has submitted copy of invoice No. EXP/321/20-21 dated 18-05-2020 for import of 1000kg of Metformin HCl (Batch# MEF/10041416) in name of M/s Titlis Pharma (Pvt.) Limited attested by AD (I&E) DRAP Lahore dated 25-06-2020. • Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers at accelerated conditions only and not at real time conditions

Decision: Approved with innovator's specifications and following label claim:
Each film coated Tablet contains:
Dapagliflozin propanediol monohydrate eq. to Dapagliflozin ……...5mg
Metformin Hydrochloride…….…..1000mg

- **Firm shall submit the differential fee of Rs. 30,000/- for correction/pre-approval change in composition (correction/change of salt factor of the drug substance) and correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Firm shall perform test for quantification of propylene glycol content in dapagliflozin drug substance by drug substance manufacturer as recommended by innovator product review document before issuance of registration letter**
- **Firm shall submit Compatibility studies of the Drug Substance(s) with excipients as the qualitative composition of the formulation is not similar to innovator / reference product before issuance of registration letter**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1861.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17526 dated 15/06/2022
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022

		(Slip#23068996766)
	The proposed proprietary name / brand name	Linet 2.5mg/500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin ……. 2.5mg Metformin Hydrochloride ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor & Biguanide (antidiabetic)
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JENTADUETO 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (linagliptin/metformin hydrochloride) film coated Tablets USFDA Approved Trajentamet (linagliptin/metformin hydrochloride) 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg film coated Tablets TGA Approved JENTADUETO (linagliptin/metformin hydrochloride) 2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000mg film coated tablets Health Canada Approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	**Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Linagliptin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03)

		Metformin Hydrochloride: Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Not submitted
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.

STABILITY STUDY DATA

Manufacturer of API	**<u>Linagliptin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155		
API Lot No.	<u>Linagliptin</u> L-20210123-D01-L09-02 <u>Metformin Hydrochloride</u> MEF/10041416		
Description of Pack (Container closure system)	ALU-ALU blister packed in cardboard unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LP-04	LP-05	LP-06
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	Nov-2021	Nov-2021	Nov-2021
Date of Initiation	20-12-2021	20-12-2021	20-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**<u>Linagliptin:</u>** The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of

		Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Metformin HCl: The firm has submitted GMP certificate for M/s Aarti Drugs Limited (Unit-II) India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 19-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Submit differential fee as the applied product is new drug molecule	
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	
1.4	• Clarification is required as the applied drug product is a New Drug Product while you have applied for generic drug product	
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for Linagliptin issued by relevant regulatory authority of country of origin	
3.2.S.4	• Justification is required for not including the test for sulphated ash in drug substance specification of drug substance metformin by drug product manufacturer as recommended by BP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method. • Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.	
3.2.S.7	• Stability study of Linagliptin drug substance batch No. L-20170604-D01-L9-03 at accelerated conditions is not submitted	
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	

	<table><tr><th>Applied product</th><th>JENTADUETO tablet</th></tr><tr><td>Linagliptin Metformin HCl</td><td>Linagliptin Metformin HCl</td></tr><tr><td>Lactose</td><td>Arginine</td></tr><tr><td>Avecil PH 102</td><td>Corn Starch</td></tr><tr><td>Starch</td><td>Copovidone</td></tr><tr><td>PVP K30</td><td>Colloidal Silicon Dioxide</td></tr><tr><td>Aerosil 200</td><td>Magnesium Stearate</td></tr><tr><td>Ac-di-sol</td><td></td></tr><tr><td>Magnesium stearate</td><td></td></tr><tr><td>Purified water</td><td></td></tr></table> • Pharmaceutical equivalence and CDP of the applied product has not been submitted. • Only protocol for CDP is submitted	
3.2.P.4	• The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications	
3.2.P.5	• Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes • Justification is required for not including test for identification test active substances and uniformity of dosage units in finished product specification as recommended by innovator product review document. • Justification is required since composition of dissolution media and rotation (0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in dissolution method for applied drug product is different than that recommended by innovator product review document (0.1N HCl and 50 rpm)	
3.2.P.8	• Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (0.1N HCl) • Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as recommended by innovator product review document. • Submit documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	

INDICATIONS AND USAGE

JENTADUETO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

JENTADUETO should not be used in patients with type 1 diabetes.

JENTADUETO has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The dosage of JENTADUETO should be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended dose of 2.5 mg linagliptin/1000 mg metformin hydrochloride (HCl) twice daily. JENTADUETO should be given twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal (GI) side effects associated with metformin use. **Recommended starting dose:** • In patients currently not treated with metformin HCl, initiate treatment with 2.5 mg linagliptin/500 mg metformin HCl twice daily. • In patients already treated with metformin HCl, start with 2.5 mg linagliptin and the current dose of metformin HCl taken at each of the two daily meals (e.g., a patient on metformin HCl 1000 mg twice daily would be started on 2.5 mg linagliptin/1000 mg metformin HCl twice daily with meals). • Patients already treated with linagliptin and metformin HCl individual components may be switched to JENTADUETO containing the same doses of each component.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.		
1862.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17527 dated 15/06/2022
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022 (Slip#6268150924)
	The proposed proprietary name / brand name	Linet 2.5mg/850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin ……. 2.5mg Metformin Hydrochloride ……. 850mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor & Biguanide (antidiabetic)
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JENTADUETO 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (linagliptin/metformin hydrochloride) film coated Tablets USFDA Approved Trajentamet (linagliptin/metformin hydrochloride) 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg film coated Tablets TGA Approved JENTADUETO (linagliptin/metformin hydrochloride) 2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000mg film coated tablets Health Canada Approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022

	Name and address of API manufacturer.	**<u>Linagliptin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**<u>Linagliptin:</u>** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) **Metformin Hydrochloride:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Jentadueto 2.5/850mg Tablet of M/s Boehringer Ingelheim Pharma Germany by performing quality tests (disintegration, weight variation, Dissolution and Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.
STABILITY STUDY DATA		
Manufacturer of API	**<u>Linagliptin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:**	

	Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155		
API Lot No.	Linagliptin L-20210123-D01-L09-02 Metformin Hydrochloride MEF/10041416		
Description of Pack (Container closure system)	ALU-ALU blister packed in cardboard unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LP-07	LP-08	LP-09
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	Nov-2021	Nov-2021	Nov-2021
Date of Initiation	31-12-2021	31-12-2021	31-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Linagliptin:** The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Metformin HCl: The firm has submitted GMP certificate for M/s Aarti Drugs Limited (Unit-II) India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 19-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Submit differential fee as the applied product is new drug molecule	
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	

<table>
<tr><td>1.4</td><td>• Clarification is required as the applied drug product is a New Drug Product while you have applied for generic drug product</td><td></td></tr>
<tr><td>1.6.5</td><td>• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for Linagliptin issued by relevant regulatory authority of country of origin</td><td></td></tr>
<tr><td>3.2.S.4</td><td>• Justification is required for not including the test for sulphated ash in drug substance specification of drug substance metformin by drug product manufacturer as recommended by BP.
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl shall be submitted.
• Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method.
• Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.</td><td></td></tr>
<tr><td>3.2.S.7</td><td>• Stability study of Linagliptin drug substance batch No. L-20170604-D01-L9-03 at accelerated conditions is not submitted</td><td></td></tr>
<tr><td>3.2.P.2</td><td>• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>JENTADUETO tablet</th></tr>
<tr><td>Linagliptin
Metformin HCl</td><td>Linagliptin
Metformin HCl</td></tr>
<tr><td>Lactose</td><td>Arginine</td></tr>
<tr><td>Avecil PH 102</td><td>Corn Starch</td></tr>
<tr><td>Starch</td><td>Copovidone</td></tr>
<tr><td>PVP K30</td><td>Colloidal Silicon Dioxide</td></tr>
<tr><td>Aerosil 200</td><td>Magnesium Stearate</td></tr>
<tr><td>Ac-di-sol</td><td></td></tr>
<tr><td>Magnesium stearate</td><td></td></tr>
<tr><td>Purified water</td><td></td></tr>
</table>
• CDP of the applied product has not been submitted.
• Only protocol for CDP is submitted</td><td></td></tr>
<tr><td>3.2.P.4</td><td>• The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications</td><td></td></tr>
<tr><td>3.2.P.5</td><td>• Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes
• Justification is required for not including test for identification test active substances and uniformity of dosage units in finished product specification as recommended by innovator product review document.
• Justification is required since composition of dissolution media and rotation (0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in</td><td></td></tr>
</table>

	dissolution method for applied drug product is different than that recommended by innovator product review document (0.1N HCl and 50 rpm)	
3.2.P.8	• Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (0.1N HCl) • Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as recommended by innovator product review document. • Submit documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	

INDICATIONS AND USAGE

JENTADUETO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

JENTADUETO should not be used in patients with type 1 diabetes.

JENTADUETO has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The dosage of JENTADUETO should be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended dose of 2.5 mg linagliptin/1000 mg metformin hydrochloride (HCl) twice daily. JENTADUETO should be given twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal (GI) side effects associated with metformin use.

Recommended starting dose:

- In patients currently not treated with metformin HCl, initiate treatment with 2.5 mg linagliptin/500 mg metformin HCl twice daily.
- In patients already treated with metformin HCl, start with 2.5 mg linagliptin and the current dose of metformin HCl taken at each of the two daily meals (e.g., a patient on metformin HCl 1000 mg twice daily would be started on 2.5 mg linagliptin/1000 mg metformin HCl twice daily with meals).
- Patients already treated with linagliptin and metformin HCl individual components may be switched to JENTADUETO containing the same doses of each component.

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

1863.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 17528 dated 15/06/2022
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022 (Slip#013889185789)
	The proposed proprietary name / brand name	Linet 2.5mg/1000mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin ……. 2.5mg Metformin Hydrochloride ……. 1000mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor & Biguanide (antidiabetic)
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JENTADUETO 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (linagliptin/metformin hydrochloride) film coated Tablets USFDA Approved Trajentamet (linagliptin/metformin hydrochloride) 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg film coated Tablets TGA Approved JENTADUETO (linagliptin/metformin hydrochloride) 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg film coated tablets Health Canada Approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	**Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies	**<u>Linagliptin:</u>** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) **Metformin Hydrochloride:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Jentadueto 2.5/1000mg Tablet of M/s Boehringer Ingelheim Pharma Germany by performing quality tests (disintegration, weight variation, Dissolution and Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.

STABILITY STUDY DATA

Manufacturer of API	**<u>Linagliptin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155		
API Lot No.	<u>Linagliptin</u> L-20210123-D01-L09-02 <u>Metformin Hydrochloride</u> MEF/10041416		
Description of Pack (Container closure system)	ALU-ALU blister packed in cardboard unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LP-10	LP-11	LP-12
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	Nov-2021	Nov-2021	Nov-2021
Date of Initiation	31-12-2021	31-12-2021	31-12-2021

No. of Batches		03
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Linagliptin:** The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Metformin HCl: The firm has submitted GMP certificate for M/s Aarti Drugs Limited (Unit-II) India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 19-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Submit differential fee as the applied product is new drug molecule	
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	
1.4	• Clarification is required as the applied drug product is a New Drug Product while you have applied for generic drug product	
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for Linagliptin issued by relevant regulatory authority of country of origin	
3.2.S.4	• Justification is required for not including the test for sulphated ash in drug substance specification of drug substance metformin by drug product manufacturer as recommended by BP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method.	

<table>
<tr><td></td><td>• Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.</td><td></td></tr>
<tr><td>3.2.S.7</td><td>• Stability study of Linagliptin drug substance batch No. L-20170604-D01-L9-03 at accelerated conditions is not submitted</td><td></td></tr>
<tr><td>3.2.P.2</td><td>• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.
<table>
<tr><th>Applied product</th><th>JENTADUETO tablet</th></tr>
<tr><td>Linagliptin
Metformin HCl</td><td>Linagliptin
Metformin HCl</td></tr>
<tr><td>Lactose</td><td>Arginine</td></tr>
<tr><td>Avecil PH 102</td><td>Corn Starch</td></tr>
<tr><td>Starch</td><td>Copovidone</td></tr>
<tr><td>PVP K30</td><td>Colloidal Silicon Dioxide</td></tr>
<tr><td>Aerosil 200</td><td>Magnesium Stearate</td></tr>
<tr><td>Ac-di-sol</td><td></td></tr>
<tr><td>Magnesium stearate</td><td></td></tr>
<tr><td>Purified water</td><td></td></tr>
</table>
• CDP of the applied product has not been submitted.
• Only protocol for CDP is submitted</td><td></td></tr>
<tr><td>3.2.P.4</td><td>• The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications</td><td></td></tr>
<tr><td>3.2.P.5</td><td>• Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes
• Justification is required for not including test for identification test active substances and uniformity of dosage units in finished product specification as recommended by innovator product review document.
• Justification is required since composition of dissolution media and rotation (0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in dissolution method for applied drug product is different than that recommended by innovator product review document (0.1N HCl and 50 rpm)</td><td></td></tr>
<tr><td>3.2.P.8</td><td>• Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (0.1N HCl)
• Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as recommended by innovator product review document.
• Accelerated stability study of Batch No#LP-12 at 3rd month time point is not submitted
• Submit documents for procurement of API with approval from DRAP
• Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td></td></tr>
</table>

	• Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	

INDICATIONS AND USAGE

JENTADUETO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

JENTADUETO should not be used in patients with type 1 diabetes.

JENTADUETO has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The dosage of JENTADUETO should be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended dose of 2.5 mg linagliptin/1000 mg metformin hydrochloride (HCl) twice daily. JENTADUETO should be given twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal (GI) side effects associated with metformin use.

Recommended starting dose:

- In patients currently not treated with metformin HCl, initiate treatment with 2.5 mg linagliptin/500 mg metformin HCl twice daily.
- In patients already treated with metformin HCl, start with 2.5 mg linagliptin and the current dose of metformin HCl taken at each of the two daily meals (e.g., a patient on metformin HCl 1000 mg twice daily would be started on 2.5 mg linagliptin/1000 mg metformin HCl twice daily with meals).
- Patients already treated with linagliptin and metformin HCl individual components may be switched to JENTADUETO containing the same doses of each component.

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

1864.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12952 dated 27/05/2022
	Details of fee submitted	PKR 30,000/-: dated 28/03/2022 (Slip#4224820319)
	The proposed proprietary name / brand name	Linatit 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin ……. 5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor (antidiabetic)
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tradjenta 5mg film coated tablets USFDA Approved.

	For generic drugs (me-too status)	Linvesta 5mg Tablet by M/s Wilshire Laboratories (Reg#110608)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Trajenta 5mg tablet of West-Ward Columbus USA by performing quality tests (Disintegration time, weight variation, Dissolution, Assay) and results are within specifications and comparable with Tradjenta 5mg Tablet.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China.
API Lot No.	L-20210123-D01-L09-02
Description of Pack (Container closure system)	ALU-ALU blister packed in cardboard unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LP-01	LP-02	LP-03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	Nov-2021	Nov-2021	Nov-2021
Date of Initiation	20-12-2021	20-12-2021	20-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	
3.2.S.4	• Justification is required for not including the test for water content, melting temperature and enantiomeric purity in drug substance specification by drug substance manufacturer as recommended by innovator's product review document. • Copies of the specifications and analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	

Applied product	**TRADJENTA tablet**
Linagliptin	Linagliptin
Lactose	Mannitol

	<table><tr><td>Avecil PH 102</td><td>Pregelatinized starch</td></tr><tr><td>Ac-Di-Sol</td><td>Corn Starch</td></tr><tr><td>Aerosil 200</td><td>Copovidone</td></tr><tr><td>PVP K30</td><td>Magnesium Stearate</td></tr><tr><td>Magnesium stearate</td><td></td></tr><tr><td>Purified water</td><td></td></tr></table> • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator/comparator product including the tests recommended by innovator product (identification, loss on drying, uniformity of dosage units). • Submit details of innovator / reference product including batch numbers, manufacturing & expiry date, name of manufacturer in pharmaceutical equivalence • (manufacturer of tradjenta 5mg tablet is Boehringer Ingelheim Pharmaceuticals while firm stated West-Ward Columbus USA) • CDP of the applied product has not been submitted. • Only protocol for CDP is submitted	
3.2.P.4	• The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications	
3.2.P.5	• Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes • Justification is required for not including test for identification of active substances, loss on drying and uniformity of dosage units in finished product specification as recommended by innovator product review document. • Justification is required since dissolution apparatus, composition of dissolution media and rotation speed (rpm) (Apparatus II, 0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in dissolution method for applied drug product is different than that recommended by innovator product review document (Apparatus I (Basket), 01N HCl and 50 rpm)	
3.2.P.8	• Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (1N HCl) • Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT Q in 30minutes as recommended by innovator product review document. • The submitted chromatograms show that the detection wavelength used during dissolution test of stability study of all the batches at initial time point is different than that given in analytical procedure, clarification is required (275nm used instead of 267nm) • Submit documents for procurement of API with approval from DRAP	

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

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

1865.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26943 dated 23/09/2022
	Details of fee submitted	PKR 30,000/-: dated 09/09/2022 (Slip#1900631731)
	The proposed proprietary name / brand name	Montit 4mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contain Montelukast Sodium equivalent to Montelukast …….4mg
	Pharmaceutical form of applied drug	Sachet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists (LTRAs)
	Reference to Finished product specifications	USP
	Proposed Pack size	14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Montelukast 4 mg Granules MHRA Approved
	For generic drugs (me-too status)	Montika 4mg Sachet by M/s Sami Pharmaceuticals (Reg#50744)
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China 317016
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical

		procedures, batch analysis and justification of specification, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (201310301, 201310302, 201310303)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Montiget Sachet 4mg of M/s Getz Pharma by performing quality tests (weight variation, Assay, Dissolution, of dosage form).
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, accuracy and precision.

STABILITY STUDY DATA

Manufacturer of API	Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China 317016		
API Lot No.	11001-210505		
Description of Pack (Container closure system)	Aluminum foil (three layer) sachet packet packed in cardboard carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MT-01	MT-02	MT-03
Batch Size	200 sachet	200 sachet	200 sachet
Manufacturing Date	Nov-2021	Nov-2021	Nov-2021
Date of Initiation	02-12-2021	02-12-2021	02-12-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate No. ZJ20180033 of M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., No.15, Donghai 5th Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City, Zhejiang Province, China issued by China Food and Drug Administration valid till 14-03-2023

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No# TY121643 dated 12th July 2021 in the name of M/s Titlis Pharma Lahore from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd., for import of 20kg Montelukast Sodium Batch No# 11001-210505. ***However the invoice is not attested by AD (I&E) DRAP field office***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated)

Remarks of Evaluator [XI]:

<table>
<tr><th>Section</th><th>Observations</th><th>Response</th></tr>
<tr><td>1.3.2</td><td>• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required</td><td></td></tr>
<tr><td>3.2.S.4</td><td>• Justification is required for not including the test for enantiomeric purity in drug substance specification by drug product manufacturer as recommended by USP.
• Firm have used isocratic method for assay test with mobile phase composition of solution A and solution B (40:60) while USP recommends gradient method
Table 1
<table>
<tr><th>Time (min)</th><th>Solution A (%)</th><th>Solution B (%)</th></tr>
<tr><td>0</td><td>60</td><td>40</td></tr>
<tr><td>3.0</td><td>60</td><td>40</td></tr>
<tr><td>16.0</td><td>49</td><td>51</td></tr>
</table>
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
• Submit readable copy of Certificate of Analysis of the same batch of drug substance used during product development and stability studies from Drug Substance manufacturer.</td><td></td></tr>
<tr><td>3.2.S.5</td><td>• COA of primary / secondary reference standard including source and lot number shall be provided.</td><td></td></tr>
<tr><td>3.2.P.2</td><td>• Justify the difference in qualitative composition of applied product from that of reference / innovator product.
<table>
<tr><td>Applied product</td><td>Montelukast 4 mg Granules</td></tr>
<tr><td>Montelukast sodium</td><td>Montelukast sodium</td></tr>
<tr><td>Dextrose</td><td>Mannitol</td></tr>
<tr><td></td><td>Hydroxy propyl cellulose</td></tr>
<tr><td></td><td>Tribasic sodium phosphate</td></tr>
<tr><td></td><td>Magnesium Stearate</td></tr>
</table>
• Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?
• CDP of the applied product has not been submitted.
• Only protocol for CDP is submitted</td><td></td></tr>
<tr><td>3.2.P.5</td><td>• Clarification is required as the method of preparation and concentration of standard solution in analytical method of dissolution test is different from USP.
• Firm have used isocratic method for assay test with mobile phase composition of solution A and solution B (30:70) while USP recommends gradient method</td><td></td></tr>
</table>

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	48	52
5	45	55
12	45	55
22	25	75
23	25	75
25	48	52
30	48	52

3.2.P.6	• Clarification is required since the submitted COA of reference / working standard states that it follows in house specifications while the product monograph is available in USP	
3.2.P.8	• Submit DRAP attested documents for the procurement of API. • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time conditions)	

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

Case No. 02: Registration applications of New Section of Human drugs on Form 5-F (Local)

M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
The Central Licensing Board in its 276th meeting held on 3rd September, 2020 has considered and approved the following additional section of M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha. under Drug Manufacturing License No. 000609 (Formulation) vide approval letter No. F. 1-37/2003-Lic (Vol-I) dated 29th September 2020.

S No.	Section
	Capsule (General) Section (New)
	Sachet (General) Section (New)

Following applications have been submitted for registration by the firm.

1866.	Name, address of Applicant / Marketing Authorization Holder	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29207 dated 26-10-2021
	Details of fee submitted	PKR 30,000/-: dated 20-10-2021

	The proposed proprietary name / brand name	PREQUAP 50 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Pregabalin…….50 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsule USFDA Approved
	For generic drugs (me-too status)	Zeegap 50mg Capsule by M/s Hilton Pharmaceuticals (Reg# 047358)
	GMP status of the Finished product manufacturer	New sections
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 60 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. Batches: (D5248-14-002, D5248-14-003, D5248-14-004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Lyrica 50 mg Capsule by Pfizer by performing quality tests (Description, Assay, Dissolution, weight variation). CDP has been performed against the same brand Lyrica 50 mg Capsule by Pfizer in Acid media 0.1N HCl (pH

		1.2), ***Phosphate Buffer*** (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision,-

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China		
API Lot No.	D5248-19-069		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T04	T05	T06
Batch Size	1500 Cap	1500 Cap	1500 Cap
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	05-02-2021	05-02-2021	05-02-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted that Quaper Pvt. Ltd is a new license facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	***GMP cetificate of M/s Zhejiang Huahai Pharmaceutical Co., Ltd Xunqiao, Linhai, Zhejiang is submitted while manufacturer is*** M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm have submitted data of stability batches along with respective documents like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	***Not applicable. Our HPLC system are not 21CFR compliant***
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm have submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.15-1.5.20	• Commitments not submitted as per the CTD guidance document	Commitments are not submitted
1.6.5	• Drug Manufacturing License (DML) / Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin	***Firm has submitted GMP certificate No. ZJ20180073 of M/s Zhejiang Huahai Pharmaceutical Co., Ltd Xunqiao, Linhai, Zhejiang China valid upto 25-06-2023 instead of*** M/s Zhejiang Huahai Pharmaceutical Co., Ltd.

	shall be submitted as the submitted GMP certificate is of different manufacturing site	Chuannan, Duqiao, Linhai, Zhejiang, 317016, China ***The submitted GMP certificate of the drug substance manufacturer of different manufacturing site.***
3.2.S.4.2	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required. • In analytical procedure in assay test you have mentioned the conc. Of standard and sample solution as 2mg/ml while in validation of analytical procedure you have mentioned the conc. Of standard and sample solution as 1mg/ml, justify?	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer ***is not submitted.*** • The firm submitted that the concentration of 1mg/1ml is to cover the lower range of assay.
3.2.S.4.3	• Results for specificity of drug substance not given by drug product manufacturer	Firm has submitted result of specificity test in analytical method verification studies for drug substance
3.2.S.5	• The Retest Date Mentioned on COA of Reference Standards or Materials is 07.2018, clarify whether the same was used for test and analysis?	Firm has not submitted clarification regarding retest date of Reference Standards or Materials. However, firm has submitted COA of USP reference standard catalog No. 1559618.
3.2.P.2	• Justification is required as Phosphate buffer ph 4.5 was used instead of acetate buffer ph 4.5 in CDP studies	The firm submitted that it was a typographical error, CDP was performed in Acetate buffer of pH 4.5 in addition to pH 1.2 and pH 6.8 buffers.
3.2.P.5.1	• You have mentioned innovators specifications in module I section 1.5.6 while in house specifications in control of drug product section 3.2.P.5.1 and 3.2.P.5.4, clarify? • Justify the acceptance criteria of dissolution test NLT Q in 45min in product specifications since FDA review documents specifies that dissolution criteria shall be NLT Q in 30 min for the applied product • Justification is required as the registration board in its 293rd meeting decided that For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator /reference product with reference to dissolution specification will not be acceptable.	• Te firm submitted that since the applied product was non pharmaopeial at the time of development at the time of development hence, we had applied for "innovator's specifications" as mentioned in section 1.5.6. • The firm submitted that for dissolution test we adopted the general provision for immediate release dosage forms and both 30min and 45mn time point are admissible for immediate release dosage form. • The firm submitted that we have revised the drug product specification as per latest BP monograph for "Pregabalin capsule" and same will be adopted for commercial batches and submit BP monograph for applied product.
3.2.P.5.2	• Details of analytical method for drug substance has been submitted against the drug product. • Justify the adoption of dissolution parameters including dissolution media (0.06N HCl)	• Analytical method for drug product is not submitted. • Te firm submitted that since the applied product was non pharmaopeial at the time of development at the time of development hence, we had applied for "innovator's specifications" but now on the issuance of BP monograph for "Pregabalin capsule" in latest edition, the same has been adopted. Same dissolution media (0.06M HCl) is mentioned in BP monograph.
3.2.P.5.3	• Results for specificity of drug product not given by drug product manufacturer	Firm has submitted results of specificity test in method validation studies for applied product
3.2.P.5.4	• In batch analysis acceptance criteria set for average weight of Batch No. T-05 is 225.00mg±7.5% while the results are 201.00mg, justify your results?	The firm submitted that it was a typographical error, the actual average weight is 200mg and limit for weight variation as 200.00mg±7.5 (Limit: 185mg-215mg) as evident from section 3.2.P.2.and COAs of other trial batches.

3.2.P.8	• Submit Raw data sheets of stability studies containing calculation formula for both assay & dissolution test • In COA for stability study acceptance criteria set for average weight of Batch No. T-04 is 225.00mg±7.5% (Limit; 208.125mg-241.875mg) while the results are 203.00mg at initial time point, 202.00mg at 3rd month time point of real time stability study, 200.00mg at 6th month time point real time stability study, justify your results? Furthermore, the acceptance criteria set for average weight of other batches are 200.00mg±7.5% (Limit; 185mg-215mg) • The injection volume mentioned in the submitted analytical method is 20µl while 10µl in the submitted chromatogram, clarify? • Submit documents for the procurement of API with approval from DRAP	• The firm submitted that same calculation formulas have been applied in calculation of assay and dissolution results as given in drug product test method. ***However, Raw data sheets of stability studies containing calculation formula for both assay & dissolution test is not submitted*** • The firm submitted that it was a typographical error, the actual average weight is 200mg and limit for weight variation as 200.00mg±7.5 (Limit: 185mg-215mg) as evident from section 3.2.P.2.and COAs of other trial batches. • ***The firm submitted that change in injection volume is within permissible limits of USP general chapter <621>*** • Firm has submitted copy of invoice No# HH20200723R1 dated 12th December 2020 in name of M/s Quaper Pvt Ltd from M/s Zhejiang Huahai Pharmaceutical Co., Ltd for import of 1.114kg Pregabalin batch No#D5248-19-069. ***However, the invoice not attested by AD (I&E) DRAP field office.*** • The firm also submitted copy of goods decalaration certificate.

Decision: Deferred for following:

- **Submission of commitments as per the Form5F guidance document**
- **Submission of GMP certificate / Drug Manufacturing License (DML) of the Drug Substance manufacturer issued by concerned regulatory authority of country of origin**
- **Submission of copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer**
- **Clarification whether the same Reference Standards or Materials was used for test and analysis of drug substance as the Retest Date Mentioned on COA of Reference Standards or Materials is 07.2018, while manufacturing date of drug substance was 23-02-3019.**
- **Submission of complete analytical method for applied drug product**
- **Submission of raw data sheets of stability studies containing calculation formula for both assay & dissolution test**
- **Clarification since the injection volume mentioned in the submitted analytical method is 20µl while 10µl in the submitted chromatogram.**
- **Submission of copy of invoice attested by AD (I&E) DRAP field office.**

1867.	Name, address of Applicant / Marketing Authorization Holder	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29208 dated 26-10-2021
	Details of fee submitted	PKR 30,000/-: dated 20-10-2021

	The proposed proprietary name / brand name	PREQUAP 75 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Pregabalin…….75 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsule USFDA Approved
	For generic drugs (me-too status)	Zeegap 75mg Capsule by M/s Hilton Pharmaceuticals (Reg# 047359)
	GMP status of the Finished product manufacturer	New sections
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 60 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. Batches: (D5248-14-002, D5248-14-003, D5248-14-004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Lyrica 75 mg Capsule by Pfizer by performing quality tests (Description, Assay, Dissolution, weight variation). CDP has been performed against the same brand Lyrica 75 mg Capsule by Pfizer in Acid media 0.1N HCl (pH

		1.2), ***Phosphate Buffer*** (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China		
API Lot No.	D5248-19-069		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T19	T20	T21
Batch Size	1500 Cap	1500 Cap	1500 Cap
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	04-02-2021	04-02-2021	04-02-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted that Quaper Pvt. Ltd is a new license facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	***GMP certificate of M/s Zhejiang Huahai Pharmaceutical Co., Ltd Xunqiao, Linhai, Zhejiang is submitted while manufacturer is*** M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm have submitted data of stability batches along with respective documents like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	***Not applicable. Our HPLC system are not 21CFR compliant***
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm have submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.15-1.5.20	• Commitments not submitted as per the CTD guidance document	Commitments are not submitted
1.6.5	• Drug Manufacturing License (DML) / Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin shall be submitted as the submitted	***Firm has submitted GMP certificate No. ZJ20180073 of M/s Zhejiang Huahai Pharmaceutical Co., Ltd Xunqiao, Linhai, Zhejiang China valid upto 25-06-2023 instead of*** M/s Zhejiang Huahai Pharmaceutical Co.,

	GMP certificate is of different manufacturing site	Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China ***The submitted GMP certificate of the drug substance manufacturer of different manufacturing site.***
3.2.S.4.2	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required. • In analytical procedure in assay test you have mentioned the conc. Of standard and sample solution as 2mg/ml (as per USP) while in validation of analytical procedure you have mentioned the conc. Of standard and sample solution as 1mg/ml, justify?	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer ***is not submitted.*** • The firm submitted that the concentration of 1mg/1ml is to cover the lower range of assay.
3.2.S.4.3	Results for specificity of drug substance not given by drug product manufacturer	Firm has submitted result of specificity test in analytical method verification studies for drug substance
3.2.S.5	The Retest Date Mentioned on COA of Reference Standards or Materials is 07.2018, clarify whether the same was used for test and analysis?	Firm has not submitted clarification regarding retest date of Reference Standards or Materials. However, firm has submitted COA of USP reference standard catalog No. 1559618.
3.2.P.2	Justification is required as Phosphate buffer ph 4.5 was used instead of acetate buffer ph 4.5 in CDP studies	The firm submitted that it was a typographical error, CDP was performed in Acetate buffer of pH 4.5 in addition to pH 1.2 and pH 6.8 buffers.
3.2.P.5.1	• You have mentioned innovators specifications in module I section 1.5.6 while in house specifications in control of drug product section 3.2.P.5.1 and 3.2.P.5.4, clarify? • Justify the acceptance criteria of dissolution test NLT Q in 45min in product specifications since FDA review documents specifies that dissolution criteria shall be NLT Q in 30 min for the applied product • Justification is required as the registration board in its 293rd meeting decided that For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator /reference product with reference to dissolution specification will not be acceptable.	• Te firm submitted that since the applied product was non pharmaopeial at the time of development at the time of development hence, we had applied for "innovator's specifications" as mentioned in section 1.5.6. • The firm submitted that for dissolution test we adopted the general provision for immediate release dosage forms and both 30min and 45min time point are admissible for immediate release dosage form. • The firm submitted that we have revised the drug product specification as per latest BP monograph for "Pregabalin capsule" and same will be adopted for commercial batches and submit BP monograph for applied product.
3.2.P.5.2	• Details of analytical method for drug substance has been submitted against the drug product. • Justify the adoption of dissolution parameters including dissolution media (0.06N HCl)	• Analytical method for drug product is not submitted. • Te firm submitted that since the applied product was non pharmaopeial at the time of development at the time of development hence, we had applied for "innovator's specifications" but now on the issuance of BP monograph for "Pregabalin capsule" in latest edition, the same has been adopted. Same dissolution media (0.06M HCl) is mentioned in BP monograph.
3.2.P.5.3	• Results for specificity of drug product not given by drug product manufacturer	Firm has submitted results of specificity test in method validation studies for applied product
3.2.P.8	• Submit Raw data sheets of stability studies containing calculation formula for both assay & dissolution test • The injection volume mentioned in the submitted analytical method is 20µl while 10µl in the submitted chromatogram, clarify • Submit documents for the procurement of API with approval from DRAP	• The firm submitted that same calculation formulas have been applied in calculation of assay and dissolution results as given in drug product test method. ***However, Raw data sheets of stability studies containing calculation formula for both assay & dissolution test is not submitted***

		• ***The firm submitted that change in injection volume is within permissible limits of USP general chapter <621>*** • Firm has submitted copy of invoice No# HH20200723R1 dated 12th December 2020 in name of M/s Quaper Pvt Ltd from M/s Zhejiang Huahai Pharmaceutical Co., Ltd for import of 1.114kg Pregabalin batch No#D5248-19-069. ***However, the invoice not attested by AD (I&E) DRAP field office.*** • The firm also submitted copy of goods decalaration certificate.

Decision: Deferred for following:

- **Submission of commitments as per the CTD guidance document**
- **Submission of GMP certificate / Drug Manufacturing License (DML) of the Drug Substance manufacturer issued by concerned regulatory authority of country of origin**
- **Submission of copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer**
- **Clarification whether the same Reference Standards or Materials was used for test and analysis of drug substance as the Retest Date Mentioned on COA of Reference Standards or Materials is 07.2018, while manufacturing date of drug substance was 23-02-3019.**
- **Submission of complete analytical method for applied drug product**
- **Submission of raw data sheets of stability studies containing calculation formula for both assay & dissolution test**
- **Clarification since the injection volume mentioned in the submitted analytical method is 20µl while 10µl in the submitted chromatogram.**
- **Submission of copy of invoice attested by AD (I&E) DRAP field office.**

1868.	Name, address of Applicant / Marketing Authorization Holder	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Name, address of Manufacturing site.	M/s Quaper (Pvt) Ltd. 26-A, Small Industrial Estate, Lahore Road, Sargodha.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29209 dated 26-10-2021
	Details of fee submitted	PKR 30,000/-: dated 20-10-2021
	The proposed proprietary name / brand name	PREQUAP 100 mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Pregabalin…….100 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	LYRICA (25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg) Capsule USFDA Approved
	For generic drugs (me-too status)	Zeegap 100mg Capsule by M/s Hilton Pharmaceuticals (Reg# 047360)
	GMP status of the Finished product manufacturer	New sections
	Name and address of API manufacturer.	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 60 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months. Batches: (D5248-14-002, D5248-14-003, D5248-14-004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Lyrica 100 mg Capsule by Pfizer by performing quality tests (Description, Assay, Dissolution, weight variation). CDP has been performed against the same brand Lyrica 100 mg Capsule by Pfizer in Acid media 0.1N HCl (pH 1.2), ***Phosphate Buffer*** (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
API Lot No.	D5248-19-069
Description of Pack	Alu-Alu blister packed in unit carton

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 Cap	1500 Cap	1500 Cap
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	06-02-2021	06-02-2021	06-02-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted that Quaper Pvt. Ltd is a new license facility hence no such inspection has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	***GMP certificate of M/s Zhejiang Huahai Pharmaceutical Co., Ltd Xunqiao, Linhai, Zhejiang is submitted while manufacturer is*** M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm have submitted data of stability batches along with respective documents like chromatograms, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	***Not applicable. Our HPLC system are not 21CFR compliant***
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm have submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.15-1.5.20	• Commitments not submitted as per the CTD guidance document	Commitments are not submitted
1.6.5	• Drug Manufacturing License (DML) / Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin shall be submitted as the submitted GMP certificate is of different manufacturing site	***Firm has submitted GMP certificate No. ZJ20180073 of M/s Zhejiang Huahai Pharmaceutical Co., Ltd Xunqiao, Linhai, Zhejiang China valid upto 25-06-2023 instead of*** M/s Zhejiang Huahai Pharmaceutical Co., Ltd. Chuannan, Duqiao, Linhai, Zhejiang, 317016, China ***The submitted GMP certificate of the drug substance manufacturer of different manufacturing site.***
3.2.S.4.2	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required. • In analytical procedure in assay test you have mentioned the conc. Of standard and sample solution as 2mg/ml (as per USP)	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer ***is not submitted.*** • The firm submitted that the concentration of 1mg/1ml is to cover the lower range of assay.

	while in validation of analytical procedure you have mentioned the conc. Of standard and sample solution as 1mg/ml, justify?	
3.2.S.4.3	• Results for specificity of drug substance not given by drug product manufacturer	Firm has submitted result of specificity test in analytical method verification studies for drug substance
3.2.S.5	• The Retest Date Mentioned on COA of Reference Standards or Materials is 07.2018, clarify whether the same was used for test and analysis?	Firm has not submitted clarification regarding retest date of Reference Standards or Materials. However, firm has submitted COA of USP reference standard catalog No. 1559618.
3.2.P.2	• Justification is required as Phosphate buffer ph 4.5 was used instead of acetate buffer ph 4.5 in CDP studies • Specify the batch number of innovator product against which pharmaceutical equivalence and CDP was performed	• The firm submitted that it was a typographical error, CDP was performed in Acetate buffer of pH 4.5 in addition to pH 1.2 and pH 6.8 buffers. • ***The firm has not submitted*** Batch number of innovator product against which pharmaceutical equivalence and CDP
3.2.P.5.1	• You have mentioned innovators specifications in module I section 1.5.6 while in house specifications in control of drug product section 3.2.P.5.1 and 3.2.P.5.4, clarify? • Justify the acceptance criteria of dissolution test NLT Q in 45min in product specifications since FDA review documents specifies that dissolution criteria shall be NLT Q in 30 min for the applied product • Justification is required as the registration board in its 293rd meeting decided that For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator /reference product with reference to dissolution specification will not be acceptable.	• Te firm submitted that since the applied product was non pharmaopeial at the time of development at the time of development hence, we had applied for "innovator's specifications" as mentioned in section 1.5.6. • The firm submitted that for dissolution test we adopted the general provision for immediate release dosage forms and both 30min and 45min time point are admissible for immediate release dosage form. • The firm submitted that we have revised the drug product specification as per latest BP monograph for "Pregabalin capsule" and same will be adopted for commercial batches and submit BP monograph for applied product.
3.2.P.5.2	• Details of analytical method for drug substance has been submitted against the drug product. • Justify the adoption of dissolution parameters including dissolution media (0.06N HCl)	• Analytical method for drug product is not submitted. • Te firm submitted that since the applied product was non pharmaopeial at the time of development at the time of development hence, we had applied for "innovator's specifications" but now on the issuance of BP monograph for "Pregabalin capsule" in latest edition, the same has been adopted. Same dissolution media (0.06M HCl) is mentioned in BP monograph.
3.2.P.5.3	• Results for specificity of drug product not given by drug product manufacturer	Firm has submitted results of specificity test in method validation studies for applied product
3.2.P.8	• Submit Raw data sheets of stability studies containing calculation formula for both assay & dissolution test • The injection volume mentioned in the submitted analytical method is 20µl while 10µl in the submitted chromatogram, clarify? • Submit documents for the procurement of API with approval from DRAP	• The firm submitted that same calculation formulas have been applied in calculation of assay and dissolution results as given in drug product test method. ***However, Raw data sheets of stability studies containing calculation formula for both assay & dissolution test is not submitted*** • ***The firm submitted that change in injection volume is within permissible limits of USP general chapter <621>*** • Firm has submitted copy of invoice No# HH20200723R1 dated 12th December 2020 in name of M/s Quaper Pvt Ltd from M/s Zhejiang Huahai Pharmaceutical Co., Ltd for import of 1.114kg Pregabalin batch No#D5248-19-069. ***However, the invoice not attested by AD (I&E) DRAP field office.***

		• The firm also submitted copy of goods decalaration certificate.

Decision: Deferred for following:

- **Submission of commitments as per the CTD guidance document**
- **Submission of GMP certificate / Drug Manufacturing License (DML) of the Drug Substance manufacturer issued by concerned regulatory authority of country of origin**
- **Submission of copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer**
- **Clarification whether the same Reference Standards or Materials was used for test and analysis of drug substance as the Retest Date Mentioned on COA of Reference Standards or Materials is 07.2018, while manufacturing date of drug substance was 23-02-3019.**
- **Submission of details of innovator product including batch number against wich pharmaceutical equivalence and CDP studies is performed**
- **Submission of complete analytical method for applied drug product**
- **Submission of raw data sheets of stability studies containing calculation formula for both assay & dissolution test**
- **Clarification since the injection volume mentioned in the submitted analytical method is 20µl while 10µl in the submitted chromatogram.**
- **Submission of copy of invoice attested by AD (I&E) DRAP field office.**

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

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

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

Following applications have been submitted for registration by the firm.

1869.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13411; dated 02/06/2022
	Details of fee submitted	PKR 30,000/-: dated 27/05/2022

	The proposed proprietary name / brand name	Carazole 30mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Lansoprazole as enteric coated pellets (8.5%)……..30mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PREVACID (15mg, 30mg) delayed-release capsules, USFDA approved
	For generic drugs (me-too status)	Caralans 30mg capsule by M/s Caraway Pharmaceuticals (Reg#50809)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (LPS0129, LPS0134, LPS0141)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Caralans 30mg capsule by Caraway Pharmaceuticals by performing quality tests (Identification, Assay, Dissolution).

		CDP has been performed against the same brand that is Caralans 30mg capsule by Caraway Pharmaceuticals in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Not submitted

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591		
API Lot No.	LPS0382		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 capsules	2500 capsules	2500 capsules
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	06-12-2021	06-12-2021	06-12-2021
No. of Batches	03		

Administrative Portion

19.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
20.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	No document submitted
22.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm have submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, summary data sheets etc.
23.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
24.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Submit valid GMP certificate of the Drug Substance manufacturer	• The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm have submitted Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3
3.2.S.4.	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer is required." • Drug substance manufacturer have claimed USP specifications while monograph for lansoprazole enteric coated pellets are not available in USP., clarification is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• Firm have submitted Copies of analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer. ***However, Copies of the Drug substance specifications by Drug Product manufacturer is not submitted.*** • The firm submitted that API manufacturer claimed and followed USP specifications because Lansoprazole pellets are delayed release and ready to fill in capsule. • Firm have submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance
3.2.S.4.4	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.	• Firm have submitted results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture.
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph (uniformity of dosage units, loss on drying). • Justification is required since pharmaceutical equivalence and CDP studies have not been conducted against the innovator product. • A minimum of three time-points should be included for CDP, the time-points for both reference (comparator) and test product being the same as per WHO guidelines while you have performed at only one time points i.e. 15 min, justification is required	• ***No justification submitted*** • Fir submitted that study conducted we me-too product due to unavailability of innovator product • The firm has submitted CDP considering multiple time points for both reference (comparator) and test product. CDP has been performed against the same brand that is Caralans 30mg capsule by Caraway Pharmaceuticals in Acid media (pH 1.0-1.2), acetate buffer (pH 5.5) & Phosphate Buffer (pH 6.8).
3.2.P.5	• Justification is required since the submitted specification does not include tests for uniformity of dosage units and loss on drying as recommended by USP. • Justification shall be submitted as the concentration and method of sample and standard solution preparation in assay test is different than that recommended by USP. • Justification is required since drug product manufacturer have proposed 20µl injection volume in chromatographic conditions in assay test instead of 10µl as recommended by USP. • Results of Analytical method verification studies of drug product performed by drug product manufacturer including	• The firm has submitted revised specifications and included tests for uniformity of dosage units and loss on drying as recommended by USP. • The firm have submitted revised method of sample and standard solution preparation in assay test having same concentration of both standard and sample solution. • The firm submitted that writing of 20µl injection volume instead of 10µl injection volume in chromatographic conditions in assay was a human error/typing mistake • Firm have submitted results of Analytical method verification studies of drug product performed by drug product manufacturer including specificity, repeatability (method precision) and accuracy.

	specificity, repeatability (method precision) and accuracy shall be submitted	
3.2.P.8	• Justification is required as 6th month stability study is performed at 04-05-2022 while trial batches are manufactured at 12-2021 before due time (01 month before) of all batches as depicted from raw data sheet and chromatograms at real time and accelerated conditions • COA of the stability batches throughout the stability study is not submitted • Test of uniformity of dosage unit has not been performed at the time of batch release, justify? • Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	• The firm submitted that 6th month stability study was conducted as realized the provided study was 5th month. The firm has submitted stability study at 6th month time point • ***COA of the stability batches throughout the stability study is not submitted*** • The firm submitted that content uniformity was conducted at the time of batch release but not mentioned in COA of the product. The firm requested to consider the COA of the product submitted now. ***However, the firm have not submitted COA of the product*** • Firm have not submitted documents for the procurement of API • Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted • Compliance record of HPLC software 21CFR & audit trail reports on product testing is not submitted.

Previous Decision (321-DRB):
Deferred for following:

- Submission of Copies of the Drug substance specifications by Drug product manufacturer
- Submission of justification as the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph i.e., uniformity of dosage units, loss on drying.
- Submission of COA of the stability batches throughout the stability study
- Submission of record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Response of the Firm:

- Copies of the Drug substance specifications by Drug product manufacturer is not submitted instead Copies of the Drug substance specifications by drug substance manufacturer is submitted
- Firm has submitted pharmaceutical equivalence study of the drug product and the comparator product including the tests recommended by USP monograph (uniformity of dosage units, loss on drying).
- Firm has submitted COA of the stability batches throughout the stability study. ***However, results for loss on drying and uniformity of dosage unit (content uniformity) test are not included in submitted COA. Furthermore, rpm mentioned in COA is 100 rpm istead of 75rpm at acid stage release and time point at buffer stage is 30 min instead of 60 minute as recommended by USP.***
- Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: Approved.

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

Registration letter will be issued upon submission of following:

- **Copies of the Drug substance specifications by Drug product manufacturer.**
- **Data for next time point of long term stability studies including performance of "loss on drying", "uniformity of dosage unit (content uniformity") and "dissolution test" as recommended by USP monongraph.**
- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

1870.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer Pharmaceuticals Industries., plot No. 27 Main Road, Rawat Industrial Estate, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19659; dated 05/07/2022
	Details of fee submitted	PKR 30,000/-: dated 21/06/2022
	The proposed proprietary name / brand name	Caraconazole 100mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Itraconazole as enteric coated pellets……100mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	***PPI***
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sporanox 100mg capsule USFDA Approved
	For generic drugs (me-too status)	Rolac 100mg capsule by M/s Sami Pharmaceuticals, (Reg#024491)
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container

		closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 06 months 06 months real time stability of two batches ICZ1464, ICZ1465 is submitted while three months real time stability study of one batch ICZ1466 is submitted. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Only 03 months accelerated stability study data of batch ICZ1466 is submitted. Batches: (ICZ1464, ICZ1465, ICZ1466)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand POLAC 100mg capsule by SAMI Pharmaceuticals by performing quality tests (Assay). CDP has been performed against the same POLAC 100mg capsule by SAMI Pharmaceuticals in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and in Acid media (0.1N HCl with 0.25% w/v SLS).
	Analytical method validation/verification of product	Not submitted.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591		
API Lot No.	ICZ1498		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2500 capsules	2500 capsules	2500 capsules
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	13-12-2021	13-12-2021	13-12-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of M/s Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	No document submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm have submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• The applied product contains immediate release pellets while you have applied enteric coated pellets, clarify	• The firm submitted that itraconazole pellets are immediate release while enteric coated pellets was written by mistake and now rectified. The firm submitted revise label as: Each Capsule contains: Itraconazole 22.0% IR pellets equivalent to Itraconazole ……100mg
1.5.5	• You have stated that itraconazole belongs to PPI. Indicate correct Pharmacological class of the API (drug substance) with proper reference.	• The firm have revised Pharmacological class of the API (drug substance) as Antifungal agent
1.6.5	• Submit valid GMP certificate of the Drug Substance manufacturer	• The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm have submitted Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer is required." • Drug substance manufacturer have claimed USP specifications while monograph for Itraconazole IR coated pellets are not available in USP., clarification is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted. • Results of dissolution studies given in batch analysis in only 0.1N HCl without SLS, while drug substance manufacturer	• Firm have submitted Copies of analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical Ingredient by Drug Product manufacturer. ***However, Copies of the Drug substance specifications by Drug Product manufacturer is not submitted.*** • The firm submitted that API manufacturer claimed and followed USP specifications because Itraconazole pellets are ready to fill in capsule. • Firm have submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance • ***No clarification is submitted***

	uses 0.25% w/v SLS in 0.1N HCl., clarification is required	
3.2.S.7	• Stability study data of drug substance till proposed shelf life shall be submitted	• No reply submitted
3.2.P.2	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph (uniformity of dosage units, dissolution, identification). • A minimum of three time-points should be included for CDP, the time-points for both reference (comparator) and test product being the same as per WHO guidelines while you have performed at only one time points i.e. 15 min, justification is required • As per WHO guideline surfactants should be avoided in comparative dissolution testing while you have used surfactant in CDP, clarify? • Justification is required since pharmaceutical equivalence and CDP studies have not been conducted against the innovator product. • Similarity factor (F2) of the resulting comparative dissolution profiles should be calculated • The brand name of Comparator product mentioned in pharmaceutical equivalence and CDP studies is Polac 100mg capsule while the brand name of product as per available database is rolac 100mg capsule, clarification is required	• ***No justification submitted*** • Fir submitted that study conducted we me-too product due to unavailability of innovator product • The firm has submitted CDP considering multiple time points for both reference (comparator) and test product. CDP has been performed against the POLAC 100mg capsule by SAMI Pharmaceuticals in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) • ***No justification is submitted*** • Similarity factor (F2) of the resulting comparative dissolution profiles is not provided • ***No clarification is submitted***
3.2.P.5	• Detailed analytical procedures used for testing of the drug product shall be provided. • Results of Analytical method verification studies of drug product performed by drug product manufacturer including specificity, repeatability (method precision) and accuracy shall be submitted	• Firm has submitted analytical procedures used for testing of the drug product • Firm have submitted results of Analytical method verification studies of drug product performed by drug product manufacturer including specificity, repeatability (method precision) and accuracy.
3.2.P.8	• Manufacturing date of pellets as per submitted COA of drug substance manufacturer is 22-12-2021 and release date as per COA is 10-01-2022 while manufacturing of applied product is 12-2021. Justification is required • COA of the stability batches throughout the stability study is not submitted • Test of uniformity of dosage unit has not been performed at the time of batch release, justify? • Submit documents for the procurement of API • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)	• The firm submitted that COA of drug substance was not of the material received and was replaced but unfortunately submitted with the dossier. • ***COA of the stability batches throughout the stability study is not submitted*** • ***No justification is submitted*** • ***Firm has not submitted documents for the procurement of API*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted*** • ***Compliance record of HPLC software 21CFR & audit trail reports on product testing is not submitted.***

	• Compliance record of HPLC software 21CFR & audit trail reports on product testing is required.	

Previous Decision (321-DRB):
Deferred for following:

- Submission of Copies of the Drug substance specifications by Drug product manufacturer
- Submission of clarification since results of dissolution studies for drug substance (pellets) given in batch analysis in only 0.1N HCl without SLS, while drug substance manufacturer uses 0.25% w/v SLS in 0.1N HCl.
- Submission of Stability study data of drug substance till proposed shelf life as the submitted stability data is till 06th months.
- Submission of justification as the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph.
- Submission of justification for using surfactant in CDP studies which is not recommended as per WHO guideline.
- Submission of COA of the stability batches throughout the stability study
- Submission of justification for not performing test of uniformity of dosage unit at the time of batch release.
- Submission of record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Response of the Firm:

- Copies of the Drug substance specifications by Drug product manufacturer is not submitted instead Copies of the Drug substance specifications by drug substance manufacturer is submitted
- The firm has submitted revised specificaions and stated that they used same dissolution medium as was used by drug substance manufacturer.
- Firm has submitted Stability study data of drug substance as per zone IV-A conditions.

Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
Batches: (ICZ1464, ICZ1465, ICZ1466)

- Firm has submitted pharmaceutical equivalence study of the drug product and the comparator product including the tests recommended by USP monograph
- Firm has submitted CDP of applied drug product as per WHO guidelines without using surfactant. However, the release of drug product in all the three media is more than 80% while dissolution media as per USP is 0.25% (w/v) sodium lauryl sulfate in 0.1 N hydrochloric acid which shows the solubility of product in the mediu may be low.
- Firm has submitted COA of the stability batches throughout the stability study
- Firm has submitted COA of drug product mentioning weight variation test instead of content uniformity test at time of batch release.
- Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: Approved with following label claim:
Each Capsule contains:
Itraconazole 22.0% IR pellets equivalent to Itraconazole ……100mg

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

Registration letter will be issued upon submission of following:

- **Copies of the Drug substance specifications by Drug product manufacturer.**
- **Data for next time point of long term stability studies including performance of "uniformity of dosage unit (content uniformity") test as recommended by USP monongraph.**
- **CDP studies in three dissolution mediums of pH 1.2, 4.5 & 6.8, without use of surfactant.**
- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021**

Case No. 4: Deferred Routine Registration applications of Human Drugs on Form 5F (Local)

1871.	Name, address of Applicant / Marketing Authorization Holder	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Name, address of Manufacturing site.	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26524 dated 24/09/2021
	Details of fee submitted	PKR 20,000/-: dated 28/12/2020 PKR 10,000/-: dated 09/06/2021
	The proposed proprietary name / brand name	Dexopra Capsule 30mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (as dual delayed release pellets) ……..……. 30 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	**Innovator's Specifications"**
	Proposed Pack size	3x10, s capsules
	Proposed unit price	MRP Rs. 540/-
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 30 mg by M/s The Searle Company Ltd. (Reg#086978)
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 22-03-2019 based on inspection conducted on 01-03-2019
	Name and address of API manufacturer.	**Source of Pellets:** Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch

		analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DLP125T, DLP124T, DLP123T)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Dextop 30mg capsule by M/s The Searle Company Ltd Karachi by performing quality tests (Assay, Dissolution).
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, LOD, LOQ and solution stability.

STABILITY STUDY DATA

Manufacturer of API	Source of Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com		
API Lot No.	DLP 420		
Description of Pack (Container closure system)	Alu-alu Blisters, packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	T-003	***T-004***	***T-005***
Batch Size	5000 caps	***3000 caps***	***3000 caps***
Manufacturing Date	06-2019	***12/10/2021***	***15/10/2021***
Date of Initiation	27-06-2019		
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice #502094 dated 19-02-2019 for 1.2kg of Dexlansoprazole DDR Pellets

		22.5% batch # DLP420 from Vision Pharmaceuticals Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of one batch only along with chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time.

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Submit valid DML as the submitted DML has been expired on 24-11-2021 • Submit latest GMP inspection report conducted with in last three years • Submit valid GMP certificate of drug substance manufacturer	• The firm have submitted valid copy of DML issued in name of M/s Magns Pharmaceuticals on 06/06/2022 • The firm have submitted GMP certificate issued on 13-04-2022 based on inspection conducted on 11-03-2022. • The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches (T-003, T-004, T-005) of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>. ***Two more batches, Batch T-004 and T-005 was manufactured on 12/10/2021 and 15/10/2021 respectively while batch T-003 was manufactured on23/06/2019. The details of these two batches are incorporated in above table.***
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• ***Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is not submitted.*** • ***Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is not submitted.***
3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product. • Comparative dissolution profile against the innovator product shall be submitted	• ***No clarification is submitted. However pharmaceutical equivalence is again submitted. Test like content uniformity, loss on drying and identification are not performed.*** • ***The firm submitted that we have performed comparative study for assay and dissolution hence Comparative dissolution profile is not required***
3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells. • For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. • Halal certificate for gelatin shall be provided	• The firm submitted that hard gelatine capsules are easily available and having same dissolving time and behaviour and other competitors are also using gelatine capsule shell. • ***No clarification submitted*** • The firm have submitted Halal certificate for gelatin shall

3.2.P.5	• You have mentioned innovator specifications under section 1.5.6 while you have followed manufacturer specifications for applied product, justify? • The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product, justify? • Results of specificity test in method validation is not submitted • The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?	• The firm submitted that we have followed innovator's specifications. • ***The firm submitted that content uniformity test is recommended for dosage form which have API 25mg or less than 25mg in all pharmacopeia reference, so we have not performed.*** • ***Results of specificity test in method validation is not submitted*** • Firm have submitted copies of complete analysis of two batches
3.2.P.8	• Submit latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) • Submit Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Justify why you have submitted stability study data of only one batch while it is required to submit stability study data of three batches as per zone IV-A conditions • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)	• ***Inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted*** • ***Firm has not submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted***

Previous Decision (321-DRB): Deferred for following:

- Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer
- Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)
- Submission of Comparative dissolution profile against the innovator product
- Submission of results of specificity test in method validation studies of drug product
- Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.
- Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)

Response of Firm:

- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer *for drug substance(s) is not submitted instead Analytical Method validation studies for drug product is submitted*
- Comparative dissolution profile against the innovator product *is not submitted instead pharmaceutical equivalence report is again submitted.*
- *The firm submitted that in as in specificity test placebo product is required but we are using ready to fill pellets and we have no placebo pellets and specificity test of API manufacturer is attached.*
- *Stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram is not submitted as per requirement*
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) *for time in which Batch T-004 and T-005 is manufactured is submitted*
- The firm further submitted that our product Cetamol tablet has been approved in 321st meeting and we have submitted audit trial and CFR 21 compliance already but if required PEC can conduct inspection for stability data

Decision: Deferred for following:

• **Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)** • **Submission of Comparative dissolution profile against the innovator product** • **Submission of results of specificity test in method validation studies of drug product** • **Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.** • **Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)**		
1872.	Name, address of Applicant / Marketing Authorization Holder	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Name, address of Manufacturing site.	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26525 dated 24/09/2021
	Details of fee submitted	PKR 20,000/-: dated 28/12/2020 PKR 10,000/-: dated 09/06/2021
	The proposed proprietary name / brand name	Dexopra Capsule 60mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (as dual delayed release pellets) ……. 60 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	**Innovator's Specifications"**
	Proposed Pack size	3x10, s capsules
	Proposed unit price	MRP Rs. 840/-
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 60 mg by M/s The Searle Company Ltd. (Reg#086979)
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 22-03-2019 based on inspection conducted on 01-03-2019
	Name and address of API manufacturer.	**Source of Pellets:** Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DLP125T, DLP124T, DLP123T)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Dextop 60mg capsule by M/s The Searle Company Ltd Karachi by performing quality tests (Assay, Dissolution).
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, LOD, LOQ and solution stability.

STABILITY STUDY DATA

Manufacturer of API	Source of Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com		
API Lot No.	DLP 420		
Description of Pack (Container closure system)	Alu-alu Blisters, packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	T-003	***T-004***	***T-005***
Batch Size	3000 caps	***3000 caps***	***3000 caps***
Manufacturing Date	06-2019	***12/10/2021***	***15/10/2021***
Date of Initiation	27-06-2019		
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of one batch only along with chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time.

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Submit valid DML as the submitted DML has been expired on 24-11-2021 • Submit latest GMP inspection report conducted with in last three years • Submit valid GMP certificate of drug substance manufacturer	• The firm have submitted valid copy of DML issued in name of M/s Magns Pharmaceuticals on 06/06/2022 • The firm have submitted GMP certificate issued on 13-04-2022 based on inspection conducted on 11-03-2022. • The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches (T-003, T-004, T-005) of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>. ***Two more batches, Batch T-004 and T-005 was manufactured on 12/10/2021 and 15/10/2021 respectively while batch T-003 was manufactured on23/06/2019. The details of these two batches are incorporated in above table.***
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• ***Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is not submitted.*** • ***Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is not submitted.***

3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product. • Comparative dissolution profile against the innovator product shall be submitted	• ***No clarification is submitted. However pharmaceutical equivalence is again submitted. Test like content uniformity, loss on drying and identification are not performed.*** • ***The firm submitted that we have performed comparative study for assay and dissolution hence Comparative dissolution profile is not required***
3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells. • For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. • Halal certificate for gelatin shall be provided	• The firm submitted that hard gelatine capsules are easily available and having same dissolving time and behaviour and other competitors are also using gelatine capsule shell. • ***No clarification submitted*** • The firm have submitted Halal certificate for gelatin shall
3.2.P.5	• You have mentioned innovator specifications under section 1.5.6 while you have followed manufacturer specifications for applied product, justify? • The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product, justify? • Results of specificity test in method validation is not submitted • The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?	• The firm submitted that we have followed innovator's specifications. • ***The firm submitted that content uniformity test is recommended for dosage form which have API 25mg or less than 25mg in all pharmacopeia reference, so we have not performed.*** • ***Results of specificity test in method validation is not submitted*** • Firm have submitted copies of complete analysis of two batches
3.2.P.8	• Submit latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) • Submit Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Justify why you have submitted stability study data of only one batch while it is required to submit stability study data of three batches as per zone IV-A conditions • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Submit documents for the procurement of API	• ***Inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted*** • ***Firm has not submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted*** • The firm has submitted copy of invoice #800742 dated 23-09-2021 for 2.5kg of Dexlansoprazole DDR Pellets 22.5% batch # DLP775 from Vision Pharmaceuticals Islamabad.

Previous Decision (321-DRB): Deferred for following:

- Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer
- Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)

- Submission of Comparative dissolution profile against the innovator product
- Submission of results of specificity test in method validation studies of drug product
- Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.
- Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)

Response of the firm:

- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer *for drug substance(s) is not submitted instead Analytical Method validation studies for drug product is submitted*
- Comparative dissolution profile against the innovator product *is not submitted instead pharmaceutical equivalence report is again submitted.*
- *The firm submitted that in as in specificity test placebo product is required but we are using ready to fill pellets and we have no placebo pellets and specificity test of API manufacturer is attached.*
- *Stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram is not submitted as per requirement*
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) *for time in which Batch T-004 and T-005 is manufactured is submitted*
- The firm further submitted that our product Cetamol tablet has been approved in 321st meeting and we have submitted audit trial and CFR 21 compliance already but if required PEC can conduct inspection for stability data

Decision: Deferred for following:

- **Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)**
- **Submission of Comparative dissolution profile against the innovator product**
- **Submission of results of specificity test in method validation studies of drug product**
- **Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.**
- **Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)**

1873.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore,
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore,
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25925 dated 17-09-2021
	Details of fee submitted	PKR 30,000/-: dated 13-08-2021
	The proposed proprietary name / brand name	"Amacure oral granules USP 4mg"
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Montelukast sodium……4mg
	Pharmaceutical form of applied drug	Oral granule is a white granular coarse free-flowing, homogeneous solid with no extraneous particles packaged

		in polyethylene aluminium / polyester sachet which finally packed in unit carton. Each unit carton contain 10 sachet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Singulair (4mg) oral granules USFDA Approved
	For generic drugs (me-too status)	Moncid Sachet by M/s De-Mont Research Laboratories (Reg# 084056)
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 06-07-2020 based on inspection conducted on 04-03-2020
	Name and address of API manufacturer.	M/s Dhanuka Laboratories Limited., Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajhastan India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MLS-F#009/15, MLS-F#010/15, MLS-F#011/15)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the Montiget sachet by Getz pharma by performing quality tests (Appearance and assay) Firm has submitted CDP report of their applied product against Montiget sachet 4mg by Getz pharma in Acid media (pH 1.2), acetate Buffer (pH 4.5) & 0.5% sodium dodecyl sulphate solution. The values for f2 is in the acceptable range
	Analytical method validation/verification of product	Firm have submitted method verification studies including accuracy, precision and specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Dhanuka Laboratories Limited., Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajhastan India		
API Lot No.	MTS-2104004		
Description of Pack (Container closure system)	Amacure oral granule is a white granular coarse free-flowing, homogeneous solid with no extraneous particles packaged in alu-alu sachet packets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T01	T02	T03
Batch Size	2000 Sachets	2000 Sachets	2000 Sachets
Manufacturing Date	04-01-2021	06-01-2021	08-01-2021
Date of Initiation	09-01-2021	09-01-2021	09-01-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of GMP certificate #DC/A-2/WHO GMP/2019/35 dated 17-01-2019 of M/s Dhanuka Laboratories Limited., Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajhastan India valid 16-01-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice # SO/KE/2122/0011 dated 22-04-2021 for import on 5kg of Montelukast sodium Batch #MTS-2104004 attested by AD (I&E) DRAP Lahore on 30-04-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm have submitted Data of stability batches supported by attested respective documents like chromatograms and summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.5.2	• Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit. Strength of Active ingredient shall be stated clearly. In case API is in the form of salt, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc.	The firm submitted that in formulation of Amacure Oral Granules 4mg, Sachet, Montelukast is used as active ingredient. Where it is present with salt sodium. In batch formula it is clearly mentioned "4mg Montelukast is equal to 4.160mg of Montelukast sodium"
1.6.5	• Submit valid GMP certificate of drug substance manufacturer	The firm have submitted copy of GMP certificate #DC/A-2/WHO-GMP/2022/77 dated 27-01-2022

		of M/s Dhanuka Laboratories Limited., SP4-4, Industrial Area, Keshwana, Rajput, Kotputli, Shahpura, Jaipur-303108 Rajasthan India issued by Drug Control Organization Rajasthan India valid for three years from the date of issue.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies is provided
3.2.S.5	• The title of reference standard Montelukast Sodium does not relate with lot No. R035A0. Clarify? • The submitted COA of working standard for batch No#WS/19/003 mentions both limits for Montelukast Sodium and Montelukast Dicyclohexylamine in assay test, clarify?	The firm submitted that as per USP monograph of Amcure sachet oral granules Montelukast Dicyclohexamine Reference standard used for testing and we follow same. ***The firm didn't give clarification how they submitted assay test results for two different salts against the same standard***
3.2.P.2	• Details of comparator product including batch numbers, mfg & expiry date in pharmaceutical equivalence are required to be provided • Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by USP monograph (dissolution, identification, uniformity of dosage unit. • You have not performed Pharmaceutical equivalence of the applied drug with the innovator / product, justify?	• The firm have submitted details of comparator product. Montiget Sachet by M/s Getz Pharma Batch No. 686D03 Mfg date; July 2020 Expiry date; July 2022 • The firm submitted that we have done all testing of both product (Amcure sachet and Montiget Sachet), it was just human error that complete results are not listed. The firm have submitted complete analysis report with comparator. • The firm submitted that innovator product Singulair Paediatric 4mg Granule by Organon Pharma UK was not available in market and DRAP give us relaxation to do equivalence studies with me-too product
3.2.P.5	• Test for uniformity of dosage unit (content uniformity) and dissolution is not included in specifications and not performed in batch analysis although given in USP monograph of drug product, clarify? • The copies of complete analysis of at least two batches shall be provided. • Provide details of analytical columns used in analytical procedure • The title of reference standard Montelukast Sodium does not relate with lot No. R035A0. Clarify? • The submitted COA of working standard for batch No#WS/19/003 mentions both limits for Montelukast Sodium and Montelukast Dicyclohexylamine in assay test, clarify?	• The firm have submitted that we have done complete testing as per USP monograph; it was a human error that complete results are not listed. The firm submitted revised finished product specifications results • Firm has submitted copies of complete analysis of three trail batches • The firm submitted revised analytical procedure containing details of analytical column • The firm stated that submitted certificate of analysis of working standard is placed in product dossier by mistake, as we receive both COA's from vendor. The certificate of analysis received from manufacturer with working standard has both assay test limits. ***However same COA has been submitted by the firm*** • The submitted certificate of analysis is correct as manufacturer of API done testing of both forms of API collectively. But we use Montelukast sodium in our product for manufacturing. The COA received from manufacturer with working standard has both assay test limits.

3.2.P.8	• Stability data reflect that test for identification, dissolution test and uniformity of dosage unit has not been performed at initial time point and throughout stability studies at both accelerated and real time conditions, justify? • The limits for assay test in stability study data is mentioned as 90%-110% instead of 90%-108% as mentioned in USP monograph, clarify? • Submit COA, Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Compliance record of HPLC software 21CFR & audit trail reports on product testing is required. • Submit latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) • Th API was imported on 30-04-2021 while the batches were manufactured in 01-2021 before the import of API, justify the manufacturing of batches before import of API	• ***The firm has submitted revised stability summary sheets containing all test at each time points and conditions.*** • The firm submitted that al results are within limits, the term written in specifications was just a copy past error and submitted revised stability summary sheets. • The firm has submitted raw data sheet containing calculation formula for both assay & dissolution test. ***However, the firm has not submitted COA and analytical record of all batches during stability study. Raw data sheets show that the results of dissolution tests are different than that reported in summary sheets.*** • Audit trail reports on product testing is submitted • Latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted • The firm submitted Letter No. 4233/202/DRAP-AD-CD(I&) dated 20-03-2020 for ***"permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies"*** containing Montelukast sodium 5kg issued AD (I&E) DRAP Lahore

Previous Decision (321-DRB): Deferred for following:

- Submission of Scientific justification for use of Montelukast sodium as reference standard in analytical procedures instead of Montelukast dicyclohexylamine specified by USP monograph.
- Submission of COA and analytical record of all batches during stability study.
- Clarification since the results of dissolution test mentioned in Raw data sheets are different than that reported in summary sheets.
- Justification is required since the submitted copy of commercial invoice # SO/KE/2122/0011 dated 22-04-2021 has been attested by AD (I&E) DRAP Lahore dated 30-04-2021 for import of 5kg of Montelukast sodium Batch #MTS-2104004 while trial batches have been manufactured in January 2021.

Response of Firm:

- The firm has not submitted scientific justification for use of Montelukast sodium as reference standard in analytical procedures instead of Montelukast dicyclohexylamine specified by USP monograph.
- The firm have submitted COA of stability batches. However complete analytical record of all batches during stability study is not submitted
- The firm submitted that it was a typographical error and submitted revised summary sheet.
- No justification is submitted

Decision: Deferred for following:

- **Submission of Scientific justification for use of Montelukast sodium as reference standard in analytical procedures instead of Montelukast dicyclohexylamine specified by USP monograph.**
- **Submission of COA and complete analytical record of all batches during stability study.**
- **Justification is required since the submitted copy of commercial invoice # SO/KE/2122/0011 dated 22-04-2021 has been attested by AD (I&E) DRAP Lahore dated 30-04-2021 for import of 5kg of Montelukast sodium Batch #MTS-2104004 while trial batches have been manufactured in January 2021.**
- **Verification of submitted commercial invoices by DRAP Lahore since firm has submitted two invices with same particulars, except the date of sign & stamp by the AD I&E.**

Agenda of Evaluator PEC-XIII.

Case 01; Registration applications of New section (Human) drugs on Form 5F.

CLB in its 284th meeting held on 16th December 2021 has considered and approved the grant of following four (04) additional section to M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura;

- Capsule (Penicillin). – New.
- Oral Dry Powder Suspension (Penicillin). – New.
- Dry Powder Injectable (Penicillin). – New.
- Dry Powder Injectable (Carbapenem). – New.

Following applications of M/s Fynk Pharma are placed before the Board for consideration.

1874.	Name, address of Applicant / Marketing Authorization Holder	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17523 dated 15-06-2022.
	Details of fee submitted	PKR 30,000/-, Challan No: 64628423, Dated 09/06/2022.
	The proposed proprietary name / brand name	FAXCIL Cap 250 mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Amoxicillin as Trihydrate ……..…….250 mg
	Pharmaceutical form of applied drug	White to off White colored granular powder filled in hard gelatin capsule shell size '2'.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	10×10's
	Proposed unit price	700/-
	The status in reference regulatory authorities	Amoxil-250 mg, USFDA approved. *250MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons*****
	For generic drugs (me-too status)	Amoxil 250mg, GSK Karachi, Reg. No. 000213.
	GMP status of the Finished product manufacturer	New license for additional sections granted on 16/12/2021.

	Evidence of section approval	Capsule (Penicillin) section New approved vide letter No. F. 1-63/84-Lic (Vol-III) dated 27-12-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Amoxicillin trihydrate is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (000130/852/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00013/210/2009, 00013/211/2009, 00013/212/2009)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description and composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution as per monograph) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Amoxil 250 mg capsule by GSK Pharma by performing quality tests (Identification, Assay, Dissolution and microbial limit).

		CDP is also performed against the same brand that is Amoxil 250 mg Capsule, batch No. 6G8W manufactured by GSK Karachi in water as dissolution medium as per monograph.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.		
API Lot No.	000130/852/2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-01	TR-02	TR-03
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	15-02-2022	15-02-2022	15-02-2022
No. of Batches	03		

Administrative Portion		
25.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product D-Lazol 30mg capsules which was conducted on 07-09-2021 and was presented in 312th meeting of Registration Board (14 - 16 September, 2021). Report has confirmed that HPLC used in the analysis has HPLC software that is 21 CFR compliant and compliance certificate from the vendor was available. Audit trial of the system on which testing was reviewed.
26.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
27.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Performa invoice No. PL/P-INV/HO /866 dated 03-01-2022 mentioning 5kg of the active ingredient is submitted. *However, no batch number is mentioned on the invoice.*

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of GMP certificate of the finished product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection conducted on 14-11-2022.
2.	1.6.5	Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02-09-2020 on the basis of inspection conducted on 22-06-2020 is submitted.
3.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.2.2	• Uniformity of dosage unit is not performed in the pharmaceutical equivalence. Clarification shall be submitted. • Justification for the use of water as dissolution medium in the CDP studies shall be submitted.	Pharmaceutical equivalence of our product with reference product i.e Amoxil Capsules by M/s GSK Pharma was established by performing Comparative Dissolution Profile. Now we have performed the Uniformity of dosage unit by weight variation as per USP <905> and results found satisfactory. Results of reference product are compared with our product (at 9th month stability). Amoxil Capsules 250mg by M/s GSK | Faxcil Capsules 250mg by Fynk Pharma 5.9 | 7.4 Limit : AV values NMT 15 Firm has submitted that dissolution media was selected based on USP monograph, as FPP monograph is available in USP (2022) so we used the same media i.e water as mentioned in USP monograph. ***Comparative Dissolution is not as per Guidelines.***
5.	3.2.P.5.2	Sample preparation in analytical method for assay test is different from USP. As per pharmacopoeia 200mg of anhydrous amoxicillin is used whereas the FPP has provided 20mg anhydrous amoxicillin. Clarification shall be submitted.	Firm has submitted that Assay testing was carried out as per USP monograph; however, there was a clerical error while typing the analytical method, 20mg was typed instead of 200mg. We request to ignore the typographic error. They also provided corrected method.
6.	3.2.P.5.4	Batch analysis of all the three trial batches shall be submitted.	Submitted.
7.	3.2.P.8	Justification for not performing uniformity of dosage units in the stability data shall be submitted.	Firm has submitted that Uniformity of dosage unit was performed at the time of batch release as it is a critical attribute for "mixing". Since uniformity is not included taken as Stability Indicator testing parameter by different guidelines such as WHO TRS 1010 (Annex 10), so we skipped this parameter.

			However we assure to perform it on commercial batches if directed by competent authority.
8.		• In some parts of the application finished product specification has mentioned dissolution specifications of Q = 80% in 30 minutes while the official monograph has mentioned 60 minutes. Justify.	Firm has submitted that Dissolution testing was conducted as per USP monograph; however, there were some clerical mistakes while typing. In our Standard Analytical Method dissolution specifications of Q = 80% in 60 minutes is mentioned. We request to ignore the typographic error.
		• Submitted invoice for the raw material has no information regarding the lot No. manufacturing date etc. Clarification shall be submitted.	Firm has submitted that material was purchased from Pharmagen Limited Pakistan. Commercial invoice is also provided. It has mentioned API lot No. 000130-12/852/2022 *However, the batch No. mentioned in the commercial invoice is different from the API lot number used in the development studies. Development of trial batches has mentioned 000130/852/2021.*

Decision: Approved.

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

Registration letter will b eissued upon submission of following:

- **Fee of Rs. 7500/- for correction/pre-approval change in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Performance of Comparative Dissolution Profile studies against innovator product, conducted in three dissolution medias of ph 1.2, 4.5 & 6.8 along with calculation of similarity factor f2 as per relevant guidelines.**
- **Verifcation of procurement of drug substance form M/s Pharmagen Ltd.**

1875.	Name, address of Applicant / Marketing Authorization Holder	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals (Pvt.) Ltd., 19 km, G.T. Road, Kalashah Kaku, Tehsil Ferozwala, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17522 dated 15-06-2022.
	Details of fee submitted	PKR 30,000/-, Challan No: 3357810099, Dated 09/06/2022.
	The proposed proprietary name / brand name	FAXCIL Capsule 500 mg.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Amoxicillin as Trihydrate ……..…….500 mg
	Pharmaceutical form of applied drug	White to off White colored granular powder filled in hard gelatin capsule shell size '0'.
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	10×10's
	Proposed unit price	1500/-
	The status in reference regulatory authorities	Amoxil-500 mg, USFDA approved. **250MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons****
	For generic drugs (me-too status)	Amoxil 500mg, GSK Karachi, Reg. No. 006669.
	GMP status of the Finished product manufacturer	New license for additional sections granted on 16/12/2021.
	Evidence of section approval	Capsule (Penicillin) section New approved vide letter No. F. 1-63/84-Lic (Vol-III) dated 27-12-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Amoxicillin trihydrate is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (000130/852/2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (00013/210/2009, 00013/211/2009, 00013/212/2009)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description and composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution as per monograph) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Amoxil 250 mg capsule by GSK Pharma by performing quality tests (Identification, Assay, Dissolution and microbial limit). CDP is also performed against the same brand that is Amoxil 500 mg Capsule, batch No. 6G8W manufactured by GSK Karachi in water as dissolution medium as per monograph.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.		
API Lot No.	000130/852/2021		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-01	TR-02	TR-03
Batch Size	1000 Capsules	1000 Capsules	1000 Capsules
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	15-02-2022	15-02-2022	15-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product D-Lazol 30mg

		capsules which was conducted on 07-09-2021 and was presented in 312th meeting of Registration Board (14 - 16 September, 2021). Report has confirmed that HPLC used in the analysis has HPLC software that is 21 CFR compliant and compliance certificate from the vendor was available. Audit trial of the system on which testing was reviewed.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Performa invoice No. PL/P-INV/HO /866 dated 03-01-2022 mentioning 5kg of the active ingredient is submitted. ***However, no batch number is mentioned on the invoice.***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of GMP certificate of the finished product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection conducted on 14-11-2022.
2.	1.6.5	Valid copy of the GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02-09-2020 on the basis of inspection conducted on 22-06-2020 is submitted.
3.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.2.2	• Uniformity of dosage unit is not performed in the pharmaceutical equivalence. Clarification shall be submitted.	Pharmaceutical equivalence of our product with reference product i.e Amoxil Capsules by M/s GSK Pharma was established by performing Comparative Dissolution Profile. Now we have performed the Uniformity of dosage unit by weight variation as per USP <905> and results found satisfactory. Results of reference product are compared with our product (at 9th month stability).

Amoxil Capsules 250mg by M/s GSK	Faxcil Capsules 250mg by Fynk Pharma
5.9	7.4
Limit : AV values NMT 15	

		• Justification for the use of water as dissolution medium in the CDP studies shall be submitted.	Firm has submitted that dissolution media was selected based on USP monograph, as FPP monograph is available in USP (2022) so we used the same media i.e water as mentioned in USP monograph. *Comparative Dissolution is not as per Guidelines.*
5.	3.2.P.5.2	Sample preparation in analytical method for assay test is different from USP. As per pharmacopoeia 200mg of anhydrous amoxicillin is used whereas the FPP has provided 20mg anhydrous amoxicillin. Clarification shall be submitted.	Firm has submitted that Assay testing was carried out as per USP monograph; however, there was a clerical error while typing the analytical method, 20mg was typed instead of 200mg. We request to ignore the typographic error. They also provided corrected method.
6.	3.2.P.5.4	Batch analysis of all the three trial batches shall be submitted.	Submitted.
7.	3.2.P.8	Justification for not performing uniformity of dosage units in the stability data shall be submitted.	Firm has submitted that Uniformity of dosage unit was performed at the time of batch release as it is a critical attribute for "mixing". Since uniformity is not included taken as Stability Indicator testing parameter by different guidelines such as WHO TRS 1010 (Annex 10), so we skipped this parameter. However we assure to perform it on commercial batches if directed by competent authority.
8.		• In some parts of the application finished product specification has mentioned dissolution specifications of Q = 80% in 30 minutes while the official monograph has mentioned 60 minutes. Justify. • Submitted invoice for the raw material has no information regarding the lot No. manufacturing date etc. Clarification shall be submitted.	Firm has submitted that Dissolution testing was conducted as per USP monograph; however, there were some clerical mistakes while typing. In our Standard Analytical Method dissolution specifications of Q = 80% in 60 minutes is mentioned. We request to ignore the typographic error. Firm has submitted that material was purchased from Pharmagen Limited Pakistan. Commercial invoice is also provided. It has mentioned API lot No. 000130-12/852/2022 *However, the batch No. mentioned in the commercial invoice is different from the API lot number used in the development studies. Development of trial batches has mentioned 000130/852/2021.*

Decision: Approved.

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

Registration letter will b eissued upon submission of following:

- **Fee of Rs. 7500/- for correction/pre-approval change in specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Performance of Comparative Dissolution Profile studies against innovator product, conducted in three dissolution medias of ph 1.2, 4.5 & 6.8 along with calculation of similarity factor f2 as per relevant guidelines.**
- **Verifcation of procurement of drug substance form M/s Pharmagen Ltd.**

CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of following 03 additional section to M/s M/s Citi Pharma (Pvt.) Ltd., 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur;

- Oral dry powder suspension (Cephalosporin)-New.
- Capsule (Cephalosporin) Section-New.
- Dry Powder Injection (Cephalosporin) – New.

Following applications are placed before the Board for consideration.

1876.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21162 dated 2707/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 1323525483 dated 05/07/2022.
	The proposed proprietary name / brand name	Ceph-Sporin Dry Powder Suspension 125/5ml.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension contain; Cephradine monohydrate Eq. to Cephradine …… 125mg.
	Pharmaceutical form of applied drug	Oral suspension.
	Pharmacotherapeutic Group of (API)	1st generation Cephalosporin.
	Reference to Finished product specifications	BP
	Proposed Pack size	1×90ml
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Cephradine for Suspension; Oral (125MG/5ML) and (250MG/5ML) USFDA Approved. Anspor (125MG/5ML) and (250MG/5ML) by GSK, USFDA approved. Status is discontinued in USFDA
	For generic drugs (me-too status)	Velosef 125mg Suspension, GSK Pakistan, Reg. No. 001867.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 89/2021-DRAP (AD-84281917-5101) dated 15-11-2021 on the basis of inspection conducted on 13-08-2021 is submitted.
	Evidence of approval of manufacturing facility.	Oral dry powder suspension (Cephalosporin) New section is approved vide letter No. F. 1-30/94- Lic. (Vol-II) dated 20-09-2021 is approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cephradine is available in USP & BP. Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted a document mentioning batch number for the drug substance without mentioning the condition for the stability. Furthermore, it is on plain paper. Batch No. (00202/001/2008, 00202/050/2008 & 00202/100/2008)
	Module-III (Drug Product):	The firm has submitted detail of drug product including its description and composition, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Velocef Suspension, Mfg. date 02-2021 manufactured by GSK, Pakistan performing quality tests (Identification, content Uniformity & Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
API Lot No.	Not provided.
Description of Pack (Container closure system)	Amber color bottle of 90ml.

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CPS-001	CPS-002	CPS-003
Batch Size (Scientifically rational batch size)	1000 bottles.	1000 bottles.	1000 bottles.
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

- All the undertakings are unsigned.
- Evidence of approval of applied formulation in reference regulatory authorities as defined by the Registration Board shall be submitted.
- Table for literature references is not as per format and does not include information of drug substance and drug product in other pharmacopoeias than USP and BP.
- Firm has submitted BP and USP specifications for the drug substance wherein no limits for 4,5 dihydrocepfradine are given while BP has mentioned the same. Clarify.
- Analytical method has also not mentioned any method for 4,5 dihydrocepfradine while the official monograph has mentioned. Clarify.
- Concentration of the standard and test samples are different from pharmacopoeia. Clarify.
- Chromatographic conditions i.e. flow rate and injection volume are also different from the pharmacopoeia.
- Analytical procedures by the finished product manufacturer shall be submitted.
- Verification of the drug product performed by the finished product manufacture shall be submitted.
- COA of the drug substance used in the development studies of the applied formulation from both drug substance and finished product manufacturer shall be submitted.
- COA submitted by both the drug substance and finished product manufacturer have no limits for 4,5 dihydrocepfradine

- Specifications has mentioned BP specifications for the drug substance while the reference standard provided is that of the USP. Clarify?
- Both real time and accelerated stability data for the drug substance from the drug substance manufacturer with conditions shall be submitted.
- 3.2.P.5.1 has claimed BP specifications while 1.5.6 has claimed USP.
- Stability data sheets shall be as per decision of 293rd meeting of RB with inclusion of API lot number, date of initiation & packing details etc.
- Complete six-month stability data.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Reference of previous approval of applications with stability study data of the firm (if any).
- Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

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

1877.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21653 dated 01-08-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 68688375 dated 05/07/2022.
	The proposed proprietary name / brand name	Ceph-Sporin Dry Powder Suspension 250/5ml.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension contain; Cephradine monohydrate …… 250mg.
	Pharmaceutical form of applied drug	Oral suspension.
	Pharmacotherapeutic Group of (API)	1st generation Cephalosporin.
	Reference to Finished product specifications	BP
	Proposed Pack size	1×90ml
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Nicef Syrup 250mg/5ml / Cefradine Syrup 250mg/5ml MHRA approved. Active Ingredient Per 5ml Cefradine 250 mg
	For generic drugs (me-too status)	Velosef 250mg Suspension, GSK Pakistan, Reg. No. 001868.

	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 89/2021-DRAP (AD-84281917-5101) dated 15-11-2021 on the basis of inspection conducted on 13-08-2021 is submitted.
	Evidence of approval of manufacturing facility.	Oral dry powder suspension (Cephalosporin) New section is approved vide letter No. F. 1-30/94- Lic. (Vol-II) dated 20-09-2021 is approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cephradine is available in USP & BP. Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted a document mentioning batch number for the drug substance without mentioning the condition for the stability. Furthermore, it is on plain paper. Batch No. (00202/001/2008, 00202/050/2008 & 00202/100/2008)
	Module-III (Drug Product):	The firm has submitted detail of drug product including its description and composition, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Velocef Suspension, Mfg. date 03-2021 manufactured by GSK, Pakistan performing quality tests (Identification, pH, content Uniformity & Assay).

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Amber color bottle of 90ml.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CPS-001	CPS-002	CPS-003
Batch Size (Scientifically rational batch size)	1000 bottles.	1000 bottles.	1000 bottles.
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	Label claim of the applied formulation is not in line with the reference product. Reference product has mentioned Cephradine 250mg/5ml while the applied formulation has	

		mentioned Cephradine monohydrate 250mg/5ml. Justification shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	1.5.15 to 1.5.20	All the undertakings are unsigned. Signed undertaking shall be submitted.	
4.	2.3	Table for literature references is not as per format and does not include information of drug substance and drug product in other pharmacopoeias than USP and BP.	
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
6.	3.2.S.4.1	Firm has submitted BP and USP specifications for the drug substance wherein no limits for 4,5 dihydrocepfradine are given while BP has mentioned the same. Clarify.	
7.	3.2.S.4.2	• Analytical procedures for the drug substance by the finished product manufacturer shall be submitted. • Analytical method has also not mentioned any method for 4,5 dihydrocepfradine while the official monograph has mentioned. Clarify. • Concentration of the standard and test samples in analytical procedures from the drug substance manufacturer are different from BP. Justification shall be submitted. • Chromatographic conditions i.e. flow rate and injection volume are also different from the pharmacopoeia. Justify.	
8.	3.2.S.4.3	Verification of the drug product performed by the finished product manufacture shall be submitted.	
9.	3.2.S.4.4	• Justify the physical form of the drug substance whether monohydrate or otherwise. • COA of the drug substance used in the development studies of the applied formulation from both drug substance and finished product manufacturer shall be submitted. • COA submitted by both the drug substance and finished product manufacturer have no limits for 4,5 dihydrocepfradine. Justify.	
10.	3.2.S.5	Specifications has mentioned BP specifications for the drug substance while the reference standard provided is that of the USP. Clarification shall be submitted.	
11.	3.2.S.7	Both real time and accelerated stability data for the drug substance from the drug substance manufacturer with conditions and specifications of the drug substance shall be submitted.	
12.	3.2.P.2.1	Qualitative composition of the applied formulation is different from the reference product. Justification shall be submitted.	
13.	3.2.P.5.1	Specifications has mentioned 4,5 dihydrocephalexin while BP has not mentioned any 4,5 dihydrocephalexin. Justify.	

14.	3.2.P.5.4	COAs of the finished product submitted has not quantified the Cefalexin quantity.	
15.	3.2.P.6	COAs and details of the reference standard used shall be submitted.	
16.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting of RB with inclusion of API lot number, date of initiation & packing details etc. • Justify the submitted chromatograms and also not calculating the content of 4,5 dihydrocephalexin as per BP monograph. • Complete six-month stability data for the applied formulation shall be submitted.	
17.		• Documents for the procurement of API with approval from DRAP (in case of import). • Reference of previous approval of applications with stability study data of the firm (if any). • Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

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

1878.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21654 dated 01-08-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 163191227481 dated 05/07/2022.
	The proposed proprietary name / brand name	Ceph-Sporin Capsule 250mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contain; Cephradine monohydrate Eq. to Cephradine …… 250mg.
	Pharmaceutical form of applied drug	Oral Capsule.

	Pharmacotherapeutic Group of (API)	1st generation Cephalosporin.
	Reference to Finished product specifications	BP
	Proposed Pack size	2 x 6's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Each capsule contains 250mg cefradine anhydrous, MHRA approved.
	For generic drugs (me-too status)	Velosef 250mg Capsule, GSK Pakistan, Reg. No. 001871.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 89/2021-DRAP (AD-84281917-5101) dated 15-11-2021 on the basis of inspection conducted on 13-08-2021 is submitted.
	Evidence of approval of manufacturing facility.	Capsule (Cephalosporin) New section is approved vide letter No. F. 1-30/94- Lic. (Vol-II) dated 20-09-2021 is approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cephradine is available in USP & BP. Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis (00203/013/2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted a document mentioning batch number for the drug substance without mentioning the condition for the stability. Furthermore, it is on plain paper. Batch No. (00202/001/2008, 00202/050/2008 & 00202/100/2008)
	Module-III (Drug Product):	The firm has submitted detail of drug product including its description and composition, manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Velosef Capsule 250mg by GSK, Pakistan performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has is performed against the same brand that is Velosef Capsule 250mg by GSK, Pakistan in Acid media pH 1.2, Acetate buffer 4.5 & Phosphate Buffer pH 6.8. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	Two Alu-PVC strips of 2x6's packed in standard unit carton with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CPC-001	CPC-002	CPC-003
Batch Size (Scientifically rational batch size)	1000 Capsules.	1000 Capsules.	1000 Capsules.
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Not Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	Label claim of the applied formulation is not in line with the reference product. Reference product has mentioned 250mg cefradine anhydrous while the applied formulation has mentioned Cephradine monohydrate Eq. to Cephradine 250mg. Justification shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	1.5.15 to 1.5.20	All the undertakings are unsigned. Signed undertaking shall be submitted.	
4.	2.3	Table for literature references is not as per format and does not include information of drug substance and drug product in other pharmacopoeias than USP and BP.	
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
6.	3.2.S.4.1	Firm has submitted both BP and USP specifications for the drug substance wherein no limits for 4,5 dihydrocepfradine are given while BP has mentioned the same. Clarify.	
7.	3.2.S.4.2	• Analytical procedures for the drug substance by the finished product manufacturer shall be submitted. • Analytical method has also not mentioned any method for 4,5 dihydrocepfradine while the official monograph has mentioned. Clarify. • Concentration of the standard and test samples in analytical procedures from the drug substance manufacturer are different from BP. Justification shall be submitted. • Chromatographic conditions i.e. flow rate and injection volume are also different from the pharmacopoeia. Justify.	
8.	3.2.S.4.3	Verification of the drug product performed by the finished product manufacture shall be submitted.	
9.	3.2.S.4.4	• Justify the physical form of the drug substance whether monohydrate or otherwise.	

		• Justification for use of micronized Cefradine (as evident from the submitted COA) in the Capsule dosage form shall be submitted. • COA of the drug substance used in the development studies of the applied formulation from both drug substance and finished product manufacturer shall be submitted. • COA submitted by both the drug substance and finished product manufacturer have no limits for 4,5 dihydrocepfradine. Justify.	
10.	3.2.S.5	Specifications has mentioned BP specifications for the drug substance while the reference standard provided is that of the USP. Clarification shall be submitted.	
11.	3.2.S.7	Both real time and accelerated stability data for the drug substance from the drug substance manufacturer with conditions and specifications of the drug substance shall be submitted.	
12.	3.2.P.5.1	Specifications has mentioned 4,5 dihydrocephalexin while BP has not mentioned any 4,5 dihydrocephalexin. Justify.	
13.	3.2.P.5.4	COAs of the finished product submitted has not quantified the Cefalexin quantity.	
14.	3.2.P.6	COAs and details of the reference standard used shall be submitted.	
15.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting of RB with inclusion of API lot number, date of initiation & packing details etc. • Justify the submitted chromatograms and also not calculating the content of 4,5 dihydrocephalexin as per BP monograph. • Complete six-month stability data for the applied formulation shall be submitted.	
16.		• Documents for the procurement of API with approval from DRAP (in case of import). • Reference of previous approval of applications with stability study data of the firm (if any). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
17.		Justification shall be submitted regarding the submitted chromatograms as neither system suitability nor all the three contents are calculated. BP pharmacopoeia states that assay is not valid unless, chromatograms obtained with solution (4), the resolution factor between the peaks corresponding to cefradine and cephalexin is at least 4.0.	

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

1879.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd.,

		3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21163 dated 27-07-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 54244495992 dated 05/07/2022.
	The proposed proprietary name / brand name	Ceph-Sporin Capsule 500mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contain; Cephradine monohydrate Eq. to Cephradine …… 500mg.
	Pharmaceutical form of applied drug	Oral Capsule.
	Pharmacotherapeutic Group of (API)	1st generation Cephalosporin.
	Reference to Finished product specifications	BP
	Proposed Pack size	2 x 6's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Each capsule contains 500mg cefradine anhydrous, MHRA approved.
	For generic drugs (me-too status)	Velosef 500mg Capsule, GSK Pakistan, Reg. No. 001863.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 89/2021-DRAP (AD-84281917-5101) dated 15-11-2021 on the basis of inspection conducted on 13-08-2021 is submitted.
	Evidence of approval of manufacturing facility.	Capsule (Cephalosporin) New section is approved vide letter No. F. 1-30/94- Lic. (Vol-II) dated 20-09-2021 is approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	Official monograph of Cephradine is available in USP & BP. Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis (00203/013/2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted a document mentioning batch number for the drug substance without mentioning the condition for the stability. Furthermore, it is on plain paper. Batch No. (00202/001/2008, 00202/050/2008 & 00202/100/2008)
	Module-III (Drug Product):	The firm has submitted detail of drug product including its description and composition, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Velosef Capsule 500mg by GSK, Pakistan performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has is performed against the same brand that is Velosef Capsule 500mg by GSK, Pakistan in Acid media pH 1.2, Acetate buffer 4.5 & Phosphate Buffer pH 6.8. The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.
API Lot No.	Not provided.
Description of Pack (Container closure system)	Two Alu-PVC strips of 2x6's packed in standard unit carton with leaflet.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	CPC-004	CPC-005	CPC-006
Batch Size (Scientifically rational batch size)	1000 Capsules.	1000 Capsules.	1000 Capsules.
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	11-2021	11-2021	11-2021
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	Label claim of the applied formulation is not in line with the reference product. Reference product has mentioned 500mg cefradine anhydrous while the applied formulation has mentioned Cephradine monohydrate Eq. to Cephradine 500mg. Justification shall be submitted.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	1.5.15 to 1.5.20	All the undertakings are unsigned. Signed undertaking shall be submitted.	
4.	2.3	Table for literature references is not as per format and does not include information of drug substance and drug product in other pharmacopoeias than USP and BP.	
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
6.	3.2.S.4.1	Firm has submitted both BP and USP specifications for the drug substance wherein	

		no limits for 4,5 dihydrocepfradine are given while BP has mentioned the same. Clarify.	
7.	3.2.S.4.2	• Analytical procedures for the drug substance by the finished product manufacturer shall be submitted. • Analytical method has also not mentioned any method for 4,5 dihydrocepfradine while the official monograph has mentioned. Clarify. • Concentration of the standard and test samples in analytical procedures from the drug substance manufacturer are different from BP. Justification shall be submitted. • Chromatographic conditions i.e. flow rate and injection volume are also different from the pharmacopoeia. Justify.	
8.	3.2.S.4.3	Verification of the drug product performed by the finished product manufacture shall be submitted.	
9.	3.2.S.4.4	• Justify the physical form of the drug substance whether monohydrate or otherwise. • Justification for use of micronized Cefradine (as evident from the submitted COA) in the Capsule dosage form shall be submitted. • COA of the drug substance used in the development studies of the applied formulation from both drug substance and finished product manufacturer shall be submitted. • COA submitted by both the drug substance and finished product manufacturer have no limits for 4,5 dihydrocepfradine. Justify.	
10.	3.2.S.5	Specifications has mentioned BP specifications for the drug substance while the reference standard provided is that of the USP. Clarification shall be submitted.	
11.	3.2.S.7	Both real time and accelerated stability data for the drug substance from the drug substance manufacturer with conditions and specifications of the drug substance shall be submitted.	
12.	3.2.P.5.1	Specifications has mentioned 4,5 dihydrocephalexin while BP has not mentioned any 4,5 dihydrocephalexin. Justify.	
13.	3.2.P.5.4	COAs of the finished product submitted has not quantified the Cefalexin quantity.	
14.	3.2.P.6	COAs and details of the reference standard used shall be submitted.	
15.	3.2.P.8	• Stability data sheets shall be as per decision of 293rd meeting of RB with inclusion of API lot number, date of initiation & packing details etc. • Justify the submitted chromatograms and also not calculating the content of 4,5 dihydrocephalexin as per BP monograph. • Complete six-month stability data for the applied formulation shall be submitted.	
16.		• Documents for the procurement of API with approval from DRAP (in case of import). • Reference of previous approval of applications with stability study data of the firm (if any).	

		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	
17.		Justification shall be submitted regarding the submitted chromatograms as neither system suitability nor all the three contents are calculated. BP pharmacopoeia states that assay is not valid unless, chromatograms obtained with solution (4), the resolution factor between the peaks corresponding to cefradine and cephalexin is at least 4.0.	

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

1880.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30041 dated 24-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 6386985219 dated 30/04/2022.
	The proposed proprietary name / brand name	Ceph-Sporin Injection 250mg IV/IM.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Cephradine L-Arginine eq. to Cephradine …… 250mg
	Pharmaceutical form of applied drug	Injection IV/IM.
	Pharmacotherapeutic Group of (API)	1st generation Cephalosporin.
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 20ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Velosef 250mg/vial, USFDA approved. Status is discontinued.
	For generic drugs (me-too status)	Velosef 250mg injection, GSK Pakistan, Reg. No. 001870.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 89/2021-DRAP (AD-84281917-5101) dated 15-11-2021 on the basis of inspection conducted on 13-08-2021 is submitted.

	Evidence of approval of manufacturing facility.	Dry powder injection (Cephalosporin) New section is approved vide letter No. F. 1-30/94- Lic. (Vol-II) dated 20-09-2021 is approved.
	Name and address of API manufacturer.	M/s Harbin Pharmaceutical Group Co., Ltd. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, analytical method for impurities, specifications, analytical procedures and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batch No. (A200803001, A200803002 & A200803003)
	Module-III (Drug Product):	The firm has submitted detail of drug product including its description and composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Velosef 250mg injection, Batch No. 346W manufactured by GSK, Pakistan by performing quality tests (Identification, pH, Sterility, Bacterial endotoxin & Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Harbin Pharmaceutical Group Co., Ltd. China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	1 x 20ml printed glass vial packed in standard unit carton provided with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T.CS-001	T.CS-002	T.CS-003
Batch Size (Scientifically rational batch size)	1000 Vials.	1000 Vials.	1000 Vials.
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	Not mentioned.	Not mentioned.	Not mentioned.
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.4	Proposed pack size has mentioned 1 x 20ml. Clarification shall be submitted.	
2.	1.5.15 - 1.5.20	All the undertakings are unsigned. Signed undertaking shall be submitted.	
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
4.	2.3	Table for literature references has mentioned both the USP and BP for drug substance However, Cephradine with L arginine is not available in any pharmacopoeia. Furthermore, Table for literature references is not as per format and does not include information of drug substance and drug product in other pharmacopoeias than USP and BP.	

5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
6.	3.2.S.	Drug substance part for Cephradine for injection is provided while the drug substance is Cephradine L-Arginine. Justification shall be submitted.	
7.	3.2.S.4.1	• Specifications provided by the drug product manufacturer has not mentioned any limits for L arginine. Justification shall be submitted. • Specification of the drug substance by the drug substance manufacturer shall be submitted. • USP monograph of Cephradine for injection has mentioned assay limits of 90.0 percent and not more than 115.0 percent of the labeled amount of cephradine, calculated as the sum of cephradine and cephalexin. While the specifications provided by the applicant has mentioned NLT 62% calculated as the sum of cephradine and cephalexin. Justification shall be submitted.	
8.	3.2.S.4.2	• Analytical method for the drug substance used by the drug substance manufacturer shall be submitted. • Analytical method for the assay test of the drug substance provided by the drug product manufacturer is completely different from the USP. Justify.	
9.	3.2.S.4.3	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	
10.	3.2.S.4.4	• COA of the drug substance from both the drug substance and drug product manufacturer used in the development studies shall be submitted. • COA submitted by the drug product manufacturer for the drug substance has assay results of 93.80%. Justify.	
11.	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	
12.	3.2.S.7.3	• Justification shall be submitted for overwriting the stability data condition of the drug substance in real time stability data of all the three batches. • Stability of the drug substance from the drug substance manufacturer shall be submitted.	
13.	3.2.P.3.3	Manufacturing process provided by the applicant is for injectable solution. Justify.	
14.	3.2.P.3.5	Process validation provided by the applicant is for some other product	
15.	3.2.P.5.1	Specifications for the drug product has not mentioned most of the test while they are included in USP. Sterility, Bacterial endotoxin, loss on drying, particulate matters etc.	
16.	3.2.P.5.2	Analytical procedures used for the drug product shall be submitted.	
17.	3.2.P.5.3	• Analytical procedure of assay in USP monograph is HPLC while provided method validation protocol No. QC/Ceph/MVD/012 issue date 21-11-2021 is for UV spectrophotometer. Justification shall be submitted.	

		• Method validation report No. QC/Ceph/MV/009 issue date 14-01-2022 is also for UV spectrophotometer. Justification shall be submitted.	
18.	3.2.P.5.4	Batch analysis/COAs of all the three trial batches shall be submitted.	
19.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	
20.	3.2.P.8.1	• Stability data sheets shall be as per decision of 293rd meeting with inclusion of starting of stability date and API lot number used in the development studies. • Justify the accelerated stability data of all the three trial batches with respect to the provided/submitted chromatograms as all the three trial batches have same values up to the decimal points.	
21.	3.2.P.8.3	• Justification shall be submitted for not performing sterility, bacterial endotoxin and particulate matters etc in the stability studies of the drug product. • In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	
22.		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
23.		• Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Chromatograms for all the three trial batches along with raw data sheets for each batch separately shall be submitted.	
24.		Justification shall be submitted regarding more than 5 types of signatures in the submitted dossiers.	
25.		Justification regarding the real time and accelerated stability data of all the trial batches with respect to the 500mg & 1gm strength of the same formulation as all the values are similar to the decimal points.	

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

1881.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30042 dated 24-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 50213190802 dated 30/04/2022.
	The proposed proprietary name / brand name	Ceph-Sporin Injection 500mg IV/IM.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Cephradine L-Arginine eq. to Cephradine …… 500mg
	Pharmaceutical form of applied drug	Injection IV/IM.
	Pharmacotherapeutic Group of (API)	1st generation Cephalosporin.
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 20ml.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Velosef 500mg/vial, USFDA approved. Status is discontinued.
	For generic drugs (me-too status)	Velosef 500mg injection (1 x 10ml), GSK Pakistan, Reg. No. 001866.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 89/2021-DRAP (AD-84281917-5101) dated 15-11-2021 on the basis of inspection conducted on 13-08-2021 is submitted.
	Evidence of approval of manufacturing facility.	Dry powder injection (Cephalosporin) New section is approved vide letter No. F. 1-30/94- Lic. (Vol-II) dated 20-09-2021 is approved.
	Name and address of API manufacturer.	M/s Harbin Pharmaceutical Group Co., Ltd. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing

		process and controls, analytical method for impurities, specifications, analytical procedures and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batch No. (A200803001, A200803002 & A200803003)
	Module-III (Drug Product):	The firm has submitted detail of drug product including its description and composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Velosef 500mg injection, Batch No. 9K6L manufactured by GSK, Pakistan by performing quality tests (Identification, pH, Sterility, Bacterial endotoxin & Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Harbin Pharmaceutical Group Co., Ltd. China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	1 x 20ml printed glass vial packed in standard unit carton provided with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T.CS-004	T.CS-005	T.CS-006
Batch Size (Scientifically rational batch size)	1000 Vials.	1000 Vials.	1000 Vials.
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	Not mentioned.	Not mentioned.	Not mentioned.
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.4	Proposed pack size has mentioned 1 x 20ml. Clarification shall be submitted.	
2.	1.5.15 - 1.5.20	All the undertakings are unsigned. Signed undertaking shall be submitted.	
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
4.	2.3	Table for literature references has mentioned both the USP and BP for drug substance However, Cephradine with L arginine is not available in any pharmacopoeia. Furthermore, Table for literature references is not as per format and does not include information of drug substance and drug product in other pharmacopoeias than USP and BP.	
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
6.	3.2.S.	Drug substance part for Cephradine for injection is provided while the drug substance is Cephradine L-Arginine. Justification shall be submitted.	
7.	3.2.S.4.1	• Specifications provided by the drug product manufacturer has not mentioned any limits for L arginine. Justification shall be submitted. • Specification of the drug substance by the drug substance manufacturer shall be submitted. • USP monograph of Cephradine for injection has mentioned assay limits of 90.0 percent and not more than 115.0 percent of the labeled amount of cephradine, calculated as the sum of cephradine and cephalexin. While the specifications provided by the applicant has mentioned NLT 62% calculated as the sum of cephradine and cephalexin. Justification shall be submitted.	
8.	3.2.S.4.2	• Analytical method for the drug substance used by the drug substance manufacturer shall be submitted. • Analytical method for the assay test of the drug substance provided by the drug product	

		manufacturer is completely different from the USP. Justify.	
9.	3.2.S.4.3	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	
10.	3.2.S.4.4	• COA of the drug substance from both the drug substance and drug product manufacturer used in the development studies shall be submitted. • COA submitted by the drug product manufacturer for the drug substance has assay results of 93.80%. Justify.	
11.	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	
12.	3.2.S.7.3	• Justification shall be submitted for overwriting the stability data condition of the drug substance in real time stability data of all the three batches. • Stability of the drug substance from the drug substance manufacturer shall be submitted.	
13.	3.2.P.3.3	Manufacturing process provided by the applicant is for injectable solution. Justify.	
14.	3.2.P.3.5	Process validation provided by the applicant is for some other product	
15.	3.2.P.5.1	Specifications for the drug product has not mentioned most of the test while they are included in USP. Sterility, Bacterial endotoxin, loss on drying, particulate matters etc.	
16.	3.2.P.5.2	Analytical procedures used for the drug product shall be submitted.	
17.	3.2.P.5.3	• Analytical procedure of assay in USP monograph is HPLC while provided method validation protocol No. QC/Ceph/MVD/012 issue date 21-11-2021 is for UV spectrophotometer. Justification shall be submitted. • Method validation report No. QC/Ceph/MV/009 issue date 14-01-2022 is also for UV spectrophotometer. Justification shall be submitted.	
18.	3.2.P.5.4	Batch analysis/COAs of all the three trial batches shall be submitted.	
19.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	
20.	3.2.P.8.1	• Stability data sheets shall be as per decision of 293rd meeting with inclusion of starting of stability date and API lot number used in the development studies. • Justify the accelerated stability data of all the three trial batches with respect to the provided/submitted chromatograms as all the three trial batches have same values up to the decimal points.	
21.	3.2.P.8.3	• Justification shall be submitted for not performing sterility, bacterial endotoxin and particulate matters etc in the stability studies of the drug product. • In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	

22.		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
23.		• Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. • Chromatograms for all the three trial batches along with raw data sheets for each batch separately shall be submitted.	
24.		Justification shall be submitted regarding more than 5 types of signatures in the submitted dossiers.	
25.		Justification regarding the real time and accelerated stability data of all the trial batches with respect to the 250mg & 1gm strength of the same formulation as all the values are similar to the decimal points.	

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

1882.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma (Pvt.) Ltd., Kasur.
	Name, address of Manufacturing site.	M/s Citi Pharma (Pvt.) Ltd., 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30043 dated 24-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 4793591610 dated 16/09/2022.
	The proposed proprietary name / brand name	Ceph-Sporin Injection 1gm IV/IM.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Cephradine L-Arginine eq. to Cephradine …… 1gm
	Pharmaceutical form of applied drug	Injection IV/IM.
	Pharmacotherapeutic Group of (API)	1st generation Cephalosporin.
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 20ml.
	Proposed unit price	As per SRO.

	The status in reference regulatory authorities	Velosef 1gm/vial, USFDA approved. Status is discontinued.
	For generic drugs (me-too status)	Velosef 1gm/vial injection, GSK Pakistan, Reg. No. 001869.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 89/2021-DRAP (AD-84281917-5101) dated 15-11-2021 on the basis of inspection conducted on 13-08-2021 is submitted.
	Evidence of approval of manufacturing facility.	Dry powder injection (Cephalosporin) New section is approved vide letter No. F. 1-30/94- Lic. (Vol-II) dated 20-09-2021 is approved.
	Name and address of API manufacturer.	M/s Harbin Pharmaceutical Group Co., Ltd. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, analytical method for impurities, specifications, analytical procedures and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batch No. (A200803001, A200803002 & A200803003)
	Module-III (Drug Product):	The firm has submitted detail of drug product including its description and composition, manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Velosef 1gm

		injection, Batch No. 346W manufactured by GSK, Pakistan by performing quality tests (Identification, pH, Sterility, Bacterial endotoxin & Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Harbin Pharmaceutical Group Co., Ltd. China.		
API Lot No.	Not provided.		
Description of Pack (Container closure system)	1 x 20ml printed glass vial packed in standard unit carton provided with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T.CS-007	T.CS-008	T.CS-009
Batch Size (Scientifically rational batch size)	1000 Vials.	1000 Vials.	1000 Vials.
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	Not mentioned.	Not mentioned.	Not mentioned.
No. of Batches	03		

Administrative Portion

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

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.4	Proposed pack size has mentioned 1 x 20ml. Clarification shall be submitted.	
2.	1.5.15 - 1.5.20	All the undertakings are unsigned. Signed undertaking shall be submitted.	
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	

4.	2.3	Table for literature references has mentioned both the USP and BP for drug substance However, Cephradine with L arginine is not available in any pharmacopoeia. Furthermore, Table for literature references is not as per format and does not include information of drug substance and drug product in other pharmacopoeias than USP and BP.	
5.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3.	
6.	3.2.S.	Drug substance part for Cephradine for injection is provided while the drug substance is Cephradine L-Arginine. Justification shall be submitted.	
7.	3.2.S.4.1	• Specifications provided by the drug product manufacturer has not mentioned any limits for L arginine. Justification shall be submitted. • Specification of the drug substance by the drug substance manufacturer shall be submitted. • USP monograph of Cephradine for injection has mentioned assay limits of 90.0 percent and not more than 115.0 percent of the labeled amount of cephradine, calculated as the sum of cephradine and cephalexin. While the specifications provided by the applicant has mentioned NLT 62% calculated as the sum of cephradine and cephalexin. Justification shall be submitted.	
8.	3.2.S.4.2	• Analytical method for the drug substance used by the drug substance manufacturer shall be submitted. • Analytical method for the assay test of the drug substance provided by the drug product manufacturer is completely different from the USP. Justify.	
9.	3.2.S.4.3	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	
10.	3.2.S.4.4	• COA of the drug substance from both the drug substance and drug product manufacturer used in the development studies shall be submitted. • COA submitted by the drug product manufacturer for the drug substance has assay results of 93.80%. Justify.	
11.	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.	
12.	3.2.S.7.3	• Justification shall be submitted for overwriting the stability data condition of the drug substance in real time stability data of all the three batches. • Stability of the drug substance from the drug substance manufacturer shall be submitted.	
13.	3.2.P.3.3	Manufacturing process provided by the applicant is for injectable solution. Justify.	
14.	3.2.P.3.5	Process validation provided by the applicant is for some other product	
15.	3.2.P.5.1	Specifications for the drug product has not mentioned most of the test while they are	

		included in USP. Sterility, Bacterial endotoxin, loss on drying, particulate matters etc.	
16.	3.2.P.5.2	Analytical procedures used for the drug product shall be submitted.	
17.	3.2.P.5.3	• Analytical procedure of assay in USP monograph is HPLC while provided method validation protocol No. QC/Ceph/MVD/012 issue date 21-11-2021 is for UV spectrophotometer. Justification shall be submitted. • Method validation report No. QC/Ceph/MV/009 issue date 14-01-2022 is also for UV spectrophotometer. Justification shall be submitted.	
18.	3.2.P.5.4	Batch analysis/COAs of all the three trial batches shall be submitted.	
19.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	
20.	3.2.P.8.1	• Stability data sheets shall be as per decision of 293rd meeting with inclusion of starting of stability date and API lot number used in the development studies. • Justify the accelerated stability data of all the three trial batches with respect to the provided/submitted chromatograms as all the three trial batches have same values up to the decimal points.	
21.	3.2.P.8.3	• Justification shall be submitted for not performing sterility, bacterial endotoxin and particulate matters etc in the stability studies of the drug product. • In-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided.	
22.		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	
23.		• Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. shall be submitted. • Chromatograms for all the three trial batches along with raw data sheets for each batch separately shall be submitted.	
24.		Justification shall be submitted regarding more than 5 types of signatures in the submitted dossiers.	
25.		Justification regarding the real time and accelerated stability data of all the trial batches with respect to the 250mg & 500 strength of the same formulation as all the values are similar to the decimal points.	

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

M/s Cure Laboratories (Pvt.) Ltd., Plot # 11-12, Street No. NS-2 RCCI, Industrial Estate, Rawat, Islamabad was granted following additional sections vide letter No. F. 1-13/2017-Lic dated 08-10-2020 in 276th meeting of Central Licensing Board held on 03-09-2020; i. Tablet section general. ii. Capsule section general.		
1883.	Name, address of Applicant / Marketing Authorization Holder	M/s Cure Laboratories (Pvt.) Ltd. Plot # 11-12, Street # NS-2, National Industrial Estate, Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Cure Laboratories (Pvt.) Ltd. Plot # 11-12, Street # NS-2, National Industrial Estate, Rawat, Islamabad.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8305 Dated: 30/03/2022
	Details of fee submitted	PKR 30,000/- Dated: 20/01/2022
	The proposed proprietary name / brand name	P-Panto 40mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated Tablet Contains: Pantoprazole as sodium sesquihydrate …. 40mg
	Pharmaceutical form of applied drug	Gastro resistant Tablets
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PROTONIX Delayed-Release Tablets, USFDA approved.
	For generic drugs (me-too status)	Panto Tablet, Remington Pharmaceutical, Reg. No. 029943
	GMP status of the Finished product manufacturer	Two additional sections granted by Licensing Division by Letter No. F-1-13/2017-Lic. Dated: 08th October 2020.
	Name and address of API manufacturer.	Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Distt.) Telangana State India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its Validation/verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Pantoprazole sodium is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance as per Zone-IV A.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Stability Batches: (PSS-S/18001, PSS-S/18002 & PSS-S/18003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures as per USP Monograph and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product as per Zone-IV A.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against Protium tablets, B. No. 205F29 manufactured by Abbott Laboratories by performing quality tests (Description, Identification, Avg. Weight, uniformity of dosage unit, Dissolution, and Assay, as per USP Monograph). CDP is carried out with Protium 40 mg tablets manufactured by M/s Sami pharma at three pH 1.2 KCl buffer, 4.5 Acetate Buffer & 6.8 Phosphate Buffer and also the similarity factor (f2) is calculated and found satisfactory.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal- Malkajgiri (Distt.) Telangana State India.		
API Lot No.	PSS/2007041		
Description of Pack (Container closure system)	Alu-PVC blister with 10 tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12, 18 & 24 (Months)		
Batch No.	T21006	T21007	T21008
Batch Size	23,800 Tablets	23,800 Tablets	23,800 Tablets
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	03-2021	03-2021	03-2021
No. of Batches	03		

Administrative Portion		
31.	Reference of previous approval of applications with stability study data of the firm (if any)	Seven Products are approved in 307th Meeting of Registration Board with stability Data. Loxiten 20mg Capsules, Loxiten 30mg Capsules, Loxiten 60mg Capsules, Omexa 20mg Capsules, Omexa 40mg Capsules, Lansasure 15mg Capusles and Lansasure 30mg Capsules.
32.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted.
33.	Documents for the procurement of API with approval from DRAP (in case of import).	25kg of Pantoprazole as sodium sesquihydrate USP is imported from Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal- Malkajgiri (Distt.) Telangana State India through Invoice # AE/20/0503 Dated 19-01-2021 for their export Registered product with Reg. No. 009762EX. Clearance certificate Dated: 02-02-2021 from Assistant Director I&E, DRAP, Islamabad is also attached.
34.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
35.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
36.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of Evaluator:

Sr. No.	Section	Observation	Response by the firm
	1.6.5	Valid GMP certificate of the drug substance manufacturer issued by the concerned / relevant regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. 36935/TS/2020 issued by the DCA Government of Telangana dated 22-04-2020 in the name of Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal- Malkajgiri (Distt.) Telangana State India. Valid till 22-04-2021.
1	2.3	Table of literature references for the drug substance has mentioned JP pharmacopoeia for the drug substance. Clarification is required.	Firm has submitted revised table of literature references.
	3.2.S.4	Justification for using crystalline I form of the drug substance shall be submitted.	Firm has submitted that Crystalline Form-I is mentioned in some Parts of DMF but in provided COAs of the API white to off white powder is mentioned. The actual description of the powder is almost white powder. We have contacted the supplier via email regarding crystalline form-I but they haven't responded yet.
2	3.2.S.4.2	Signed analytical procedures for drug substance by the finished product manufacturer shall be submitted.	Submitted.
3	3.2.P.2.1.2	Qualitative composition of the applied formulation is different form reference product. Clarification shall be submitted.	Still different from innovator product.
4	3.2.P.2.2.1.	• Justification of using KCl buffer in CDP shall be submitted. • Justification shall be submitted for using only one-time point in CDP in all the three mediums. • Justification for not performing CDP against the innovator product shall be submitted.	Firm has submitted new results for CDP against Zentro 40 mg Tablets, B. No. 08916F manufactured by Bosch Pharmaceuticals at three pH 1.2 HCl buffer, 4.5 Acetate Buffer & 6.8 Phosphate Buffer by using different time points instead of using only one-time point and also the similarity factor (f2) is calculated and found satisfactory. We have tried to arrange the innovator product (Protonix 40mg Tablets) but we are unable to arrange the innovator and therefore, we have performed the CDP with Brand Leader in Pakistan Zentro 40mg Tablets Mfg. By Bosch Pharma Karachi Pakistan.
5	3.2.P.3	EMA public assessment report has mentioned that "the drug substance is incompatible with all conventional gastro-resistant coating polymers, which are acidic. It was, therefore, necessary to seal the tablet core with an additional isolating layer of neutral coating material before applying the gastro-resistant coat". However, manufacturing method of the applied formulation has no such sealing or coating before enteric coating. Clarify.	Actually in the BMRs of Executed Batches we have applied seal coating before enteric coating. But in the stage of Dossier compilation the manufacturing method of seal coating may forgot to mention. But in the new CTD Dossier of P-Panto 40mg Tablets we have mentioned the complete seal coating method before enteric coating.
6	3.2.P.5.2.	Signed copy of analytical method of drug product shall be submitted.	Submitted.
7	3.2.P.5.3.	In analytical method validation data 100% concentration of the sample has an area of 550332 while the raw data sheets of stability study data have an area of 453426 for the same concentration. Clarification is required.	
8	3.2.P.8	• Stability data sheets have mentioned manufacturing date of April 2021 for the trial batches while the same sheets	***Firm has submitted new stability data vide Dy. No. 30260 dated 25-10-2022 for the applied formulation with submission of full fee of***

		have mentioned initial testing in march 2021. Clarification is required. • Submit stability data sheets as per approved format by the Registration Board with inclusion of API lot number. • Stability data sheets are for vial dosage form. Clarification is required. • Finished product specification has mentioned tablet weight of 215mg ± 3% while the raw data sheets for assay calculation has mentioned average weight content of 265mg. clarification is required. • Analytical record for dissolution test shall be provided.	***30,000/- fee vide slip No. 27965616690 dated 10-11-2022.*** ***Details of the stability data are given below;***

STABILITY STUDY DATA

Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against Zentro 40 mg Tablets, B. No. 08916F manufactured by Bosch Pharmaceuticals by performing quality tests (Description, Identification, Avg. Weight, uniformity of dosage unit, Dissolution, and Assay, as per USP Monograph). CDP is carried out with Zentro 40 mg Tablets, B. No. 08916F manufactured by Bosch Pharmaceuticals at three pH 1.2 HCl buffer, 4.5 Acetate Buffer & 6.8 Phosphate Buffer and also the similarity factor (f2) is calculated and found satisfactory.		
Manufacturer of API	Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal- Malkajgiri (Distt.) Telangana State India.		
API Lot No.	PSS/2007041		
Description of Pack (Container closure system)	Alu-PVC blister with 10 tablets.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12, 18 & 24 (Months)		
Batch No.	T22009	T22010	T22011
Batch Size	23,800 Tablets	23,800 Tablets	23,800 Tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	07-02-2022	07-02-2022	07-02-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Seven Products are approved in 307th Meeting of Registration Board with stability Data. Loxiten 20mg Capsules, Loxiten 30mg Capsules, Loxiten 60mg Capsules, Omexa 20mg Capsules, Omexa 40mg Capsules, Lansasure 15mg Capusles and Lansasure 30mg Capsules.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 36935/TS/2020 issued by the DCA Government of Telangana dated 22-04-2020 in the name of Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal-Malkajgiri (Distt.) Telangana State India. Valid till 22-04-2021.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	25kg of Pantoprazole as sodium sesquihydrate USP is imported from Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal- Malkajgiri (Distt.) Telangana State India through Invoice # AE/20/0503 Dated 19-01-2021 for their export Registered product with Reg. No. 009762EX. Clearance certificate Dated: 02-02-2021 from Assistant Director I&E, DRAP, Islamabad is also attached.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted.

Remarks of the Evaluator:

- Firm has submitted document No. L. Dis. No. 4084/A3/2019 dated 20-05-2020 in the name of Metrochem API private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road phase-I IDA, Jeedimetla, Quthbullapur (M), Medchal- Malkajgiri (Distt.) Telangana State India issued by Drugs Control Administration Government of Telangana wherein it is stated that the manufacturer confirms to requirements for Good Manufacturing Practices in the manufacturing and quality control (As recommended by the WHO) in respect of the products mentioned above (Twenty-Six in number) for export in the international market. Validity is for three years from date of issuance.
- Graphical representation of the CDP has shown more than 80% release of the drug in acidic media to which firm replied that it was presented mistakenly for another product while the tabulated results were in compliance.
- Qualitative composition is different from the innovator product. Clarify.

Decision: Approved. Firm shall submit "Drug Excipinet Compatibility" studies before issuance of registration letter.

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

Case 02; Registration applications of Locally Manufactured Routine (Human) drugs on Form 5F.

1884.	Name, address of Applicant / Marketing Authorization Holder	Pharmasol Private Limited, 82, R-1, M.A. Johar Town. Lahore.
	Name, address of Manufacturing site.	Pharmasol Private Limited, Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer. ☐ Importer.

		☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No. 34237 dated 31-12-2021.
	Details of fee submitted	PKR 30,000/-: dated 19-06-2021.
	The proposed proprietary name / brand name	Tigesol 60mg tablet.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ticagrelor …… 60mg.
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	Alu/Alu foil blister of 7's, 10's. 7's, 10's, 14's, 20's, 21's, 28's, 30's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Brilinta 60 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 60mg, PharmEvo (Pvt.) Ltd., Reg. No.093105.
	GMP status of the Finished product manufacturer	GMP certificate No. 249/2019-DRAP (AD-716018-5101) dated 21-08-2019 issued on the basis of inspection conducted on 25-07-2019 is submitted by the firm.
	Evidence of section approval.	Tablet section general, Anti-cancer & Hormone mentioned in the above submitted GMP certificate.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Yangkou Chemical Industrial park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China. Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (RD-TG-201806261, RD-TG-201808021, RD-TG-201810081)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, batch formula, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against Anplag 60 mg tablet by PharmEvo (Pvt) Ltd, Batch number 9H209, Mfg. date 07-2019, Exp. Date 06-2021 by performing quality tests (Disintegration, Assay, Dissolution). CDP has been performed against the same brand that is Anplag 60 mg tablet by PharmEvo (Pvt) Ltd in four different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer & polysorbate 80. The values for f2 are in the acceptable range and 0.2% polysorbate 80 in water. The values are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China.		
API Lot No.	RD-TG-201911211.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	UJ001	UJ002	UJ003
Batch Size	2500 tab	2500 tab	2500 tab

Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	02-09-2020	02-09-2020	02-09-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice number CY120024 dated 14-02-2020 mentioning 1.83kg quantity of ticagrelor, Batch No. RD-TG-201911211 attested by Assistant Director DRAP, Lahore vide No. 3434/2020DRAP dated 05-03-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observations.	Response by the firm.
1.	1.3.4	Valid copy of GMP certificate of the drug product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 issued on the basis of inspection conducted on 22-08-2022.
2.	1.5.6	This section has mentioned innovator specifications while the official monograph is available in BP. Clarification is required.	Firm has submitted that trial batches were developed in August, 2020, whereas, the monograph for ticagrelor tablets was published in BP in 2022, that's why trial batches were developed with innovator specifications.
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid upto 2-12-2025
4.	2.3	Table for literature references has not mentioned any pharmacopoeia neither for the drug substance nor for	Firm has submitted that at the time of development and submission of dossier, neither monograph for the drug substance nor for the

		the drug product while the official monograph for both the drug substance as well as drug product is available in BP. Justification shall be submitted.	drug product was available in any pharmacopoeia. ***Firm has not submitted any revised document for literature references.***
5.	3.2.S.4.1	• In house specification are claimed for the drug substance while the official monograph is available in BP. Justification shall be submitted. • Specifications of the drug substance by the drug product manufacturer shall be submitted.	Firm has submitted that trial batches were developed in August, 2020, whereas, the monograph for ticagrelor tablets was published in BP in 2022, that's why trial batches were developed with innovator specifications. Submitted.
6.	3.2.S.4.2	• Analytical procedure for the assay test provided by the drug substance manufacturer has no formula for the assay calculation. Clarification shall be submitted. • Analytical procedures for the drug substance by the drug product manufacturer shall be submitted	Submitted. Submitted.
7.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Firm has submitted commitment to perform method verification studies both for drug substance and drug product before commercial manufacturing. ***Firm has not submitted any verification/ validation studies for the drug substance.***
8.	3.2.S.4.4	The reference product literature specifies polymorphic form II for ticagrelor tablets whereas no such declaration has been made in the COA of drug substance.	Firm has submitted that Polymeric form II has been declared by Drug substance manufacturer under Section 3.2.S.1.3 General Properties, hence it is not mentioned on COA.
9.	3.2.S.5	Details of the reference standard or material and COA of primary / secondary reference standard including source and lot number shall be provided.	Submitted.
10.	3.2.P.2.2	• Justification of not performing Pharmaceutical Equivalence & CDP against innovator product shall be submitted. • Justification shall be submitted for carrying CDP in polysorbate medium.	Firm has submitted that as per DRAP guidelines, they have performed, Pharmaceutical Equivalence & CDP studies against comparator brand leader in local market, ANPLAG 60mg Tablets (manufactured by PharmEvo Pvt. Limited). In addition, the results were found similar and in compliance with quality test parameters. They further submitted that although the CDP was performed in 0.1N HCl, Acetate Buffer pH 4.5 & Phosphate Buffer pH 6.8. However, dissolution in 0.2% Polysorbate was additionally performed to verify the results in USFDA dissolution media.
11.	3.2.P.5.1	• This section has mentioned in-house specifications while the official monograph of the applied formulation is available in BP. • Dissolution limits provided by the drug product manufacturer (NLT 85% after 75 minutes) are different from official monograph (Q = 70% after 45 minutes). Justification shall be submitted.	Firm has again referred to the response made under point number 2.3 that the monograph for Ticagrelor tablet was not available in BP-2020 and hence product was developed as per Innovator's Specifications and the same limits had been applied. Firm has submitted that the drug product was developed as per Innovator's Specifications because of unavailability of monograph in BP-2020. However, the commercial batches shall be developed and tested as per monograph available in BP-2022.

12.	3.2.P.5.2	• Analytical method for dissolution test has mentioned phosphate buffer as medium. Clarification shall be submitted. • Analytical procedures for both the tests assay and dissolution are different from the official monograph in respect of conditions, parameters and standard preparation, sample preparation and mobile phase etc. clarification shall be submitted.	Firm has submitted that it was a typographic mistake. Dissolution media for drug product is Polysorbate 80 in water. Firm has again referred to the response made under point number 2.3 that the monograph for Ticagrelor tablet was not available in BP-2020 and hence product was developed as per Innovator's Specifications and the same limits had been applied.
13.	3.2.P.8.1	• Reference of previous approval of applications with stability study data shall be submitted.	Not submitted.
14.	3.2.P.8.3	• Justification shall be submitted for using 99.55 potency in the calculation of assay and dissolution tests of the stability studies with respect to the potency of with reference to the COA of reference / working standard material (98.7%) as per available information in the application of 90mg. • Justify the run time and retention time for ticagrelor in the submitted chromatograms as the official monograph has mentioned retention time of about 4 minutes and run time of twice the retention time.	Firm has submitted COA of the primary reference standard wherein the assay is 99.55%. Firm has again referred to the response made under point number 2.3 that the monograph for Ticagrelor tablet was not available in BP-2020 and hence product was developed as per Innovator's Specifications and the same limits had been applied.

Decision: Approved with BP specifications. The firm shall submit fee of Rs. 75,00/- for correction/pre-approval change in specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter

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

1885.	Name, address of Applicant / Marketing Authorization Holder	Pharmasol Private Limited, 82, R-1, M.A. Johar Town. Lahore.
	Name, address of Manufacturing site.	Pharmasol Private Limited, Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No. 34238 dated 31-12-2021.
	Details of fee submitted	PKR 30,000/-: dated 19-06-2021.
	The proposed proprietary name / brand name	Tigesol 90mg tablet.

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Ticagrelor …… 90mg.
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Platelet aggregation inhibitors excl. heparin.
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	Alu/Alu foil blister of 7's, 10's. 7's, 10's, 14's, 20's, 21's, 28's, 30's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Brilinta 90 mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Anplag 90mg, PharmEvo (Pvt.) Ltd., Reg. No.089382.
	GMP status of the Finished product manufacturer	GMP certificate No. 249/2019-DRAP (AD-716018-5101) dated 21-08-2019 issued on the basis of inspection conducted on 25-07-2019 is submitted by the firm.
	Evidence of section approval.	Tablet section general, Anti-cancer & Hormone mentioned in the above submitted GMP certificate.
	Name and address of API manufacturer.	M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si Road, Yangkou Chemical Industrial park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, China. Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batches: (RD-TG-201806261, RD-TG-201808021, RD-TG-201810081)
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, batch formula, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against BRILINTA by AstraZeneca, Batch number TMTK, Mfg. date 02-2019, Exp. Date 01-2022 by performing quality tests (Disintegration, Assay, Dissolution). CDP has been performed against the same brand that is BRILINTA by AstraZeneca Batch No: TMTK, Exp: 01-2022, in four BCS media across the physiological pH range i.e. 0.1 N HCl, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer and 0.2% Polysorbate 80 in water. The values are in the acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province China.		
API Lot No.	RD-TG-201911211.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	VJ001	VJ002	VJ003
Batch Size	2500 tab	2500 tab	2500 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	02-09-2020	02-09-2020	02-09-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate for M/s Nantong Chanyoo Pharmatech Co., Ltd., issued by Nantong chemical and Medical industry association valid till 05-05-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice number CY120024 dated 14-02-2020 mentioning 1.83kg quantity of ticagrelor, Batch No. RD-TG-201911211 attested by Assistant Director DRAP, Lahore vide No. 3434/2020DRAP dated 05-03-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observations.	Response by the firm.
1.	1.3.4	Valid copy of GMP certificate of the drug product manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 140/2022-DRAP (AD-084433115014) dated 26-08-2022 issued on the basis of inspection conducted on 22-08-2022.
2.	1.5.6	This section has mentioned innovator specifications while the official monograph is available in BP. Clarification is required.	Firm has submitted that trial batches were developed in August, 2020, whereas, the monograph for ticagrelor tablets was published in BP in 2022, that's why trial batches were developed with innovator specifications.
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the relevant regulatory authority shall be submitted.	Manufacturing License (No. Su 20160512) for M/s Nantong Chanyoo Pharmatech Co., Ltd., No. 2 Tonghai Si road, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, China issued by Jiangsu Food & Drug Administration valid upto 2-12-2025
4.	2.3	Table for literature references has not mentioned any pharmacopoeia neither for the drug substance nor for the drug product while the official monograph for both the drug substance as well as drug product is available in BP. Justification shall be submitted.	Firm has submitted that at the time of development and submission of dossier, neither monograph for the drug substance nor for the drug product was available in any pharmacopoeia. ***Firm has not submitted any revised document for literature references.***
5.	3.2.S.4.1	• In house specification are claimed for the drug substance while the official monograph is available in BP. Justification shall be submitted. • Specifications of the drug substance by the drug product manufacturer shall be submitted.	Firm has submitted that trial batches were developed in August, 2020, whereas, the monograph for ticagrelor tablets was published in BP in 2022, that's why trial batches were developed with innovator specifications. Submitted.

6.	3.2.S.4.2	• Analytical procedure for the assay test provided by the drug substance manufacturer has no formula for the assay calculation. Clarification shall be submitted. • Analytical procedures for the drug substance by the drug product manufacturer shall be submitted	Submitted. Submitted.
7.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted.	Firm has submitted commitment to perform method verification studies both for drug substance and drug product before commercial manufacturing. ***Firm has not submitted any verification/ validation studies for the drug substance.***
8.	3.2.S.4.4	The reference product literature specifies polymorphic form II for ticagrelor tablets whereas no such declaration has been made in the COA of drug substance.	Firm has submitted that Polymeric form II has been declared by Drug substance manufacturer under Section 3.2.S.1.3 General Properties, hence it is not mentioned on COA.
9.	3.2.P.2.2	• Justification shall be submitted for carrying CDP in polysorbate medium.	Firm has submitted that although the CDP was performed in 0.1N HCl, Acetate Buffer pH 4.5 & Phosphate Buffer pH 6.8. However, dissolution in 0.2% Polysorbate was additionally performed to verify the results in USFDA dissolution media.
10.	3.2.P.5.1	• This section has mentioned in-house specifications while the official monograph of the applied formulation is available in BP. • Dissolution limits provided by the drug product manufacturer (NLT 85% after 75 minutes) are different from official monograph (Q = 70% after 45 minutes). Justification shall be submitted.	Firm has submitted that as per DRAP guidelines, they have performed, Pharmaceutical Equivalence & CDP studies against comparator brand leader in local market, ANPLAG 60mg Tablets (manufactured by PharmEvo Pvt. Limited). In addition, the results were found similar and in compliance with quality test parameters. However, the commercial batches shall be developed and tested as per monograph available in BP 2022.
11.	3.2.P.5.2	• Analytical method for determination of assay is for 60mg tablets. Analytical method for 90mg tablet shall be submitted. • Analytical method for dissolution test has mentioned phosphate buffer as medium. Clarification shall be submitted. • Analytical procedures for both the tests assay and dissolution are different from the official monograph in respect of conditions, parameters and standard preparation, sample preparation and mobile phase etc. clarification shall be submitted.	Submitted. Firm has submitted revised method for dissolution test with Polysorbate 80 as dissolution medium. Firm has again referred to the response made under point number 2.3 that the monograph for Ticagrelor tablet was not available in BP-2020 and hence product was developed as per Innovator's Specifications and the same limits had been applied.
12.	3.2.P.8.1	• Reference of previous approval of applications with stability study data shall be submitted.	Not submitted.
13.	3.2.P.8.3	• Justification shall be submitted for using 99.55 potency in the calculation of assay and dissolution tests of the stability studies with respect to the potency of with	Firm has submitted COA of the primary reference standard wherein the assay is 99.55%.

		reference to the COA of reference / working standard material. • Justify the run time and retention time for ticagrelor in the submitted chromatograms as the official monograph has mentioned retention time of about 4 minutes and run time of twice the retention time.	Firm has again referred to the response made under point number 2.3 that the monograph for Ticagrelor tablet was not available in BP-2020 and hence product was developed as per Innovator's Specifications and the same limits had been applied.

Decision: Approved with BP specifications. The firm shall submit fee of Rs. 75,00/- for correction/pre-approval change in specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter

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

Case 03; Registration applications of New section (Human) deferred drugs on Form 5F.

On the recommendations of panel of experts, the CLB in its 273rd meeting held on 15th January, 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following four sections:

i. Tablet Section (General)
ii. Capsule Section (General)
iii. Sachet Section (General)
iv. Dry powder injection section (pre-lyophilized) vial

1886.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Name, address of Manufacturing site.	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13056: dated 28-05-2022.
	Details of fee submitted	PKR 30,000/-: dated 13/05/2022.
	The proposed proprietary name / brand name	Levosulpiride 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains Levosulpiride …….. 25mg
	Pharmaceutical form of applied drug	Tablet.
	Pharmacotherapeutic Group of (API)	Antipsychotic.
	Reference to Finished product specifications	Innovator's specifications

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Levosulpiride 25mg tablet, AIFA ITALY Approved.
	For generic drugs (me-too status)	Syconor Tablet 25mg, Opal Laboratories, Reg. No. 096116.
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020. General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized) Vial.
	Evidence of section approval.	Tablet general section is approved vide letter No. F.1-1/2016/Lic. Dataed 24-02-2020.
	Name and address of API manufacturer.	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Official monograph of Levosulpiride is not present in USP/BP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months. Batches:(ALC/LSP/180304, ALC/LSP/180305, ALC/LSP/180306).
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., B. No. AQ2309Q by performing quality tests (description, Assay, Dissolution). CDP has been performed against the same brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.		
API Lot No.	31L01Z2122-001.		
Description of Pack (Container closure system)	White colored round, biconvex, plain on the both sides core tablet, blistered in Alu-Alu.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-001
Batch Size	2000 Tablets.	2000 Tablets.	2000 Tablets.
Manufacturing Date	08-2021	09-2021	09-2021
Date of Initiation	02-09-2021	06-09-2021	11-09-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate No. S-GMP/20102297 in the name of Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India issued by the Food & Drug Control Administration Gandhinagar, Gujarat State, India valid till 21-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No. ALC/20210215 wherein quantity of 1.1kg of Levosulpiride for test/analysis is imported by the firm. The invoice is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.

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

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	3.2.S.4.1	Specifications of the drug substance by the finished product manufacturer shall be submitted.	*Firm has submitted specification for drug product instead of Drug substance.*
2.	3.2.S.4.2	Analytical procedures for the dug substance by the finished product manufacturer shall be submitted.	Submitted. *However, the assay method in the analytical procedure submitted by the drug product manufacturer is by UV method and HPLC method while the drug substance has mentioned potentiometric method for the assay of the drug substance.*
3.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	Analytical record for the drug substance shall be submitted.	Firm has submitted analytical record for the drug substance. Submitted analytical has shown hand written date of 16-08-2021 while the firm has also submitted new COA with release date of 16-08-2021. However, in the initially submitted dossier, COA with release date of 24-05-2021 was submitted. Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021.
5.	3.2.S.4.5	Justification of specifications for the drug substance shall be submitted.	*Justifications of specification submitted by the firm has assay value of 98.5% - 101% while the drug substance manufacturer has assay limits of 99% - 101%.*
6.	3.2.P.2.2	• Justification shall be submitted for not carrying the CDP against the innovator's brand. • Calculation of F2 for CDP shall be submitted.	Firm has submitted that according to WHO technical report series, No. 902,2002, if the innovator product is not available in the local market you can use the market leader product. They further submitted that in their case Levopraid 25mg tablets manufactured by Pacific pharmaceuticals under the license from Ravizza pharmaceutici S.p.A. Milan, Italy is considered appropriate for pharmaceutical equivalence studies as this product is currently widely used within our local market and repute of company and the product is also satisfactory. Firm has submitted complete calculations of F2 value for all the three mediums used in CDP.

7.	3.2.P.8	Documents for the procurement of API with approval from DRAP mentioning the batch number of the drug substance shall be submitted.	Firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021 attested by Assistant Director I&E, DRAP, Lahore dated 12-04-2021. *However, the API lot used in the formulation development studies has batch number of 31L01Z2122-001.*

Decision: Registration Board decided to defer the case for verification or submission of the following points:

- COA of the drug substance initially submitted was having release date of 24-05-2021 while the substance clearance (invoice) is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.
- Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021. Justification shall be submitted.
- API lot used in the formulation development studies has batch number of 31L01Z2122-001, while firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021.

Reply by the firm;

COA of the drug substance initially submitted was having release date of 24-05-2021 while the substance clearance (invoice) is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.	Firm has submitted that they have export registration of Levosulpiride under brand name of ***Evorant 50mg TABLET (Re g# 009908-EX).*** And we import 05kg Raw material via ***FORM 5 # 5599/2021 DRAP*** *dated* ***14-04-2021*** under invoice # **AB/I/00001/21-22** with ***AD I&E Lahore approval date 04-05-2021.*** The data of above-mentioned batch is by mistake copied and sent to you initially, upon knowing our mistake we provide you the correct data of material import via ***Form 6 # 11241/2021-DRAP*** *Approved on* ***28-07-2021*** and **Invoice # ALC/20210215** dated **15-02-2021** and **AD (I&E) approval date 28-07-2021.**
Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021. Justification shall be submitted.	We have export registration of Levosulpiride under brand name of ***Evorant 50mg TABLET (Reg # 009908-EX).*** And we import 05kg Raw material via ***Form 5 # 5599/2021 DRAP*** *DATED* ***14-04-2021*** under invoice # **AB/I/00001/21-22** with ***AD I&E Lahore approval date 04-05-2021.*** The data including Chromatograms of above-mentioned batch is by mistake copied and sent to you initially, upon knowing our mistake we provide you the correct data of material import via ***Form 6 # 11241/2021-DRAP*** *Approved on* ***28-07-2021*** and **Invoice # ALC/20210215** dated **15-02-2021** and **AD (I&E) approval date 28-07-2021**
API lot used in the formulation development studies has batch number of 31L01Z2122-001, while firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021.	As mentioned above we copied the data of commercial **(FORM-5)** drug substance instead of R&D **(FORM-6)** drug substance. We have imported the drug substance for export purpose via ***FORM 5 # 5599/2021 DRAP*** *DATED* ***14-04-2021*** under invoice # **AB/I/00001/21-22** with ***AD I&E Lahore approval date 04-05-2021.*** Initially the invoice # **AB/I/00001/21-22** was approved on 14-04-2021 with **Levosulpiride batch # LSP/N/21-001**

	Mfg. date: 02-2021, **Exp. date** 02-2024. But due to shortage of material the manufacturer excuses us to provide **batch # LSP/N/21-001** and send us documents of new batch # ***31L01Z2122-001 Mfg. date 04-2021 Exp. date: 03-2024.*** *Both of these batches are for the manufacturing of our export product EVORANT 50mg TABLET (Reg. # 009908-EX).* And for commercial purpose. While the drug substance imported for R&D under ***FORM 6 # 11241/2021-DRAP.*** *Approved on* ***28-07-2021*** and **Invoice # ALC/20210215** dated **15-02-2021** and **AD (I&E) APPROVAL DATE 28-07-2021** Contains batch # ***31L01Z2122-001 Mfg. date 04-2021 Exp date 03-2024.*** **1.1 kg** of above-mentioned batch is imported on Form-6 for CTD product development and this material is used in our R&D and CTD dossier of Levosulpiride 25mg & 50mg tablet is made keeping in mind of this material but unfortunately, we have copied the supporting data of commercial drug substance.
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	

1887.	Name, address of Applicant / Marketing Authorization Holder	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Name, address of Manufacturing site.	Variant Pharmaceuticals (Pvt.) Ltd., Plot # 5 M-2, Pharmazone, 26Km Lahore-Sharaqpur road, Sheikhupura, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13057: dated 28-05-2022.
	Details of fee submitted	PKR 30,000/-: dated 13/05/2022.
	The proposed proprietary name / brand name	Levosulpiride 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains Levosulpiride …….. 50mg
	Pharmaceutical form of applied drug	Tablet.
	Pharmacotherapeutic Group of (API)	Antipsychotic.
	Reference to Finished product specifications	Innovator's specifications

	Proposed Pack size	10's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Levosulpiride 50mg tablet, AIFA ITALY Approved.
	For generic drugs (me-too status)	Levopraid 50mg tablets, Opal Laboratories, Reg. No. 019755.
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020. General Tablet, General Capsule, General Sachet and General dry powder injectable (pre-lyophilized) Vial.
	Evidence of section approval.	Tablet general section is approved vide letter No. F.1-1/2016/Lic. Dataed 24-02-2020.
	Name and address of API manufacturer.	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Official monograph of Levosulpiride is not present in USP/BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 48 months. Batches:(ALC/LSP/180304, ALC/LSP/180305, ALC/LSP/180306).
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand that is LEVOPRAID 25 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., B. No. AP0909Q by performing quality tests (description, Assay, Dissolution). CDP has been performed against the same brand that is LEVOPRAID 50 mg Tablets by M/s Pacific Pharma (Pvt.) Ltd., in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India.		
API Lot No.	31L01Z2122-001.		
Description of Pack (Container closure system)	White colored round, biconvex, plain on the both sides core tablet, blistered in Alu-Alu.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	2000 Tablets.	2000 Tablets.	2000 Tablets.
Manufacturing Date	08-2021	09-2021	09-2021
Date of Initiation	02-09-2021	06-09-2021	11-09-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate No. S-GMP/20102297 in the name of Alcon Biosciences Private Limited, A-1/2104, phase III, GIDC, Vapi, Gujarat –396 195 India issued by the Food & Drug Control Administration Gandhinagar, Gujarat State, India valid till 21-10-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No. ALC/20210215 wherein quantity of 1.1kg of Levosulpiride for test/analysis is imported by the firm. The invoice is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.

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

Remarks of the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	3.2.S.4.1	Specifications of the drug substance by the finished product manufacturer shall be submitted.	Firm has submitted specification for drug substance. *However, the assay limits provided by the drug product manufacturer are 98.5% - 101% while that of the drug substance manufacturer are 99% - 101%.*
2.	3.2.S.4.2	Analytical procedures for the dug substance by the finished product manufacturer shall be submitted.	***Not Submitted.***
3.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
4.	3.2.S.4.4	Analytical record for the drug substance shall be submitted.	Firm has submitted analytical record for the drug substance. Submitted analytical has shown hand written date of 16-08-2021 while the firm has also submitted new COA with release date of 16-08-2021.
5.	3.2.S.4.5	Justification of specifications for the drug substance shall be submitted.	***Not Submitted.***
6.	3.2.P.2.2	• Justification shall be submitted for not carrying the CDP against the innovator's brand. • Calculation of F2 for CDP shall be submitted.	Firm has submitted that according to WHO technical report series, No. 902,2002, if the innovator product is not available in the local market you can use the market leader product. They further submitted that in their case Levopraid 50mg tablets manufactured by Pacific pharmaceuticals under the license from Ravizza pharmaceutici S.p.A. Milan, Italy is considered appropriate for pharmaceutical equivalence studies as this product is currently widely used within our local market and repute of company and the product is also satisfactory. Firm has submitted complete calculations of F2 value for all the three mediums used in CDP.
7.	3.2.P.8	Documents for the procurement of API with approval from DRAP mentioning the batch number of the drug substance shall be submitted.	Firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021 attested by Assistant Director I&E, DRAP, Lahore dated 12-04-2021. *However, the API lot used in the formulation development studies has batch number of 31L01Z2122-001.*

Decision: Registration Board decided to defer the case for verification or submission of the following points:

- COA of the drug substance initially submitted was having release date of 24-05-2021 while the substance clearance (invoice) is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.
- Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021. Justification shall be submitted.
- API lot used in the formulation development studies has batch number of 31L01Z2122-001, while firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021.

Reply by the firm;

COA of the drug substance initially submitted was having release date of 24-05-2021 while the substance clearance (invoice) is signed and stamped by the Assistant Director I&E, DRAP, Lahore dated 28-07-2021.	Firm has submitted that they have export registration of Levosulpiride under brand name of ***Evorant 50mg TABLET (Re g# 009908-EX).*** And we import 05kg Raw material via ***FORM 5 # 5599/2021 DRAP*** *dated* ***14-04-2021*** under invoice # **AB/I/00001/21-22** with ***AD I&E Lahore approval date 04-05-2021.*** The data of above-mentioned batch is by mistake copied and sent to you initially, upon knowing our mistake we provide you the correct data of material import via ***Form 6 # 11241/2021-DRAP*** *Approved on* ***28-07-2021*** and **Invoice # ALC/20210215** dated **15-02-2021** and **AD (I&E) approval date 28-07-2021.**
Furthermore, submitted chromatograms of the drug substance in the analytical record submitted by the firm has also shown processing date of 22-05-2021. Justification shall be submitted.	We have export registration of Levosulpiride under brand name of ***Evorant 50mg TABLET (Reg # 009908-EX).*** And we import 05kg Raw material via ***Form 5 # 5599/2021 DRAP*** *DATED* ***14-04-2021*** under invoice # **AB/I/00001/21-22** with ***AD I&E Lahore approval date 04-05-2021.*** The data including Chromatograms of above-mentioned batch is by mistake copied and sent to you initially, upon knowing our mistake we provide you the correct data of material import via ***Form 6 # 11241/2021-DRAP*** *Approved on* ***28-07-2021*** and **Invoice # ALC/20210215** dated **15-02-2021** and **AD (I&E) approval date 28-07-2021**
API lot used in the formulation development studies has batch number of 31L01Z2122-001, while firm has submitted commercial invoice No. AB/I/00001/21-22 dated 02-04-2021 mentioning 05kg of Levosulpiride, batch No. LSP/N/21/001, manufacturing date Feb, 2021.	As mentioned above we copied the data of commercial **(FORM-5)** drug substance instead of R&D **(FORM-6)** drug substance. We have imported the drug substance for export purpose via ***FORM 5 # 5599/2021 DRAP*** *DATED* ***14-04-2021*** under invoice # **AB/I/00001/21-22** with ***AD I&E Lahore approval date 04-05-2021.*** Initially the invoice # **AB/I/00001/21-22** was approved on 14-04-2021 with **Levosulpiride batch # LSP/N/21-001** **Mfg. date:** 02-2021, **Exp. date** 02-2024. But due to shortage of material the manufacturer excuses us to provide **batch # LSP/N/21-001** and send us documents of new batch # ***31L01Z2122-001 Mfg. date 04-2021 Exp. date: 03-2024.*** *Both of these batches are for the manufacturing of our export product EVORANT 50mg TABLET (Reg. # 009908-EX).* And for commercial purpose.

	While the drug substance imported for R&D under ***FORM 6 # 11241/2021-DRAP.*** *Approved on* ***28-07-2021*** and **Invoice # ALC/20210215** dated **15-02-2021** and **AD (I&E) APPROVAL DATE 28-07-2021** Contains batch # ***31L01Z2122-001 Mfg. date 04-2021 Exp date 03-2024.*** **1.1 kg** of above-mentioned batch is imported on Form-6 for CTD product development and this material is used in our R&D and CTD dossier of Levosulpiride 25mg & 50mg tablet is made keeping in mind of this material but unfortunately, we have copied the supporting data of commercial drug substance.

Decision: Approved.

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

Case 04; Registration applications of deferred (Human) drugs on Form 5.

1888.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224/23, Korangi Industrial Area, Karachi (Dry powder injection vials Cephalosporin).
	Brand Name + Dosage Form + Strength	Cefrinex 1gm Dry powder for injection.
	Composition	Each vial contains: 1gm sterile cephradine with sterile arginine.
	Diary No. Date of R & I & fee	Dy. No 18914 dated 24-10-2017; Rs. 20,000/- dated 31-10-2016. Duplicate File Bearing Dy. No.151 dated 19-04-2021.
	Pharmacological Group	Cephalosporin Antibiotic.
	Type of Form	Form-5.
	Finished product Specification	USP specifications.
	Pack size & Demanded Price	1's & As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Cefrinex vial 1000mg, Reg. No. 015129.
	GMP status	GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Remarks of the Evaluator	• Firm has provided Velosef 1gm injection in HPRA (Ireland) which could not be verified. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Provided evidence is discontinued.
	Decision of 316th meeting of Registration Board.	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Reply by the frim	Firm has submitted that as per decision of Registration Board in its 320th meeting held on 29 – 31 August, 2022, DRAP has decided to consider the pending applications of Cephradine injection. They further requested to consider their application for registration for Cefrinex 1gm dry powder for injection.
	Remarks of the Evaluator	•

	Decision: Approved. Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding formulation of "Cephradine for Injection" along with submission of requisite fee (if required) for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1889.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224/23, Korangi Industrial Area, Karachi (Dry powder injection vials Cephalosporin).
	Brand Name + Dosage Form + Strength	Cefrinex 250mg Injection (IV, IM)
	Composition	Each vial contains: Cephradine (as Dihydrate) with L-Arginine ……250mg
	Diary No. Date of R & I & fee	Dy.No.18912;24-10-2017; Rs.20,000/- (23-10-2017)
	Pharmacological Group	AntiBiotic
	Type of Form	Form-5.
	Finished product Specification	USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued ANSM France approved as IV only but archived on 07.05.2011
	Me-too status	Welphardine 250mg Injection M/s WelMark Pharmaceutical,
	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Remarks of the Evaluator	Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed.
	Decision of 284th meeting of Registration Board.	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Reply by the frim	Firm has submitted that as per decision of Registration Board in its 320th meeting held on 29 – 31 August, 2022, DRAP has decided to consider the pending applications of Cephradine injection. They further requested to consider their application for registration for Cefrinex 250mg dry powder for injection.
	Remarks of the Evaluator	• GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Decision: Approved. Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding formulation of "Cephradine for Injection" along with submission of requisite fee (if required) for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	
1890.	Name and address of manufacturer/ Applicant	M/s High-Q Pharmaceuticals, Plot No.224/23, Korangi Industrial Area, Karachi (Dry powder injection vials Cephalosporin).
	Brand Name + Dosage Form + Strength	Cefrinex 500mg Injection (IV, IM)
	Composition	Each vial contains: Cephradine (as Dihydrate) with L-Arginine ……500mg
	Diary No. Date of R & I & fee	Dy.No.18913; 24-10-2017; Rs.20,000/- (23-10-2017)
	Pharmacological Group	AntiBiotic
	Type of Form	Form-5.
	Finished product Specification	USP specifications.
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA discontinued. ANSM France approved as IV only but archived on 07.05.2011
	Me-too status	Veloadvan 500mg Injection M/s Advanced Pharmaceuticals,

	GMP status	Last GMP inspection was conducted on 19-07-2017 and the report shows grant of GMP certificate.
	Remarks of the Evaluator	Evidence of approval of applied formulation with active status of in market in reference regulatory authorities could not be confirmed.
	Decision of 284th meeting of Registration Board.	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Reply by the frim	Firm has submitted that as per decision of Registration Board in its 320th meeting held on 29 – 31 August, 2022, DRAP has decided to consider the pending applications of Cephradine injection. They further requested to consider their application for registration for Cefrinex 500mg dry powder for injection.
	Remarks of the Evaluator	• GMP certificate issued on 02-02-2021 on the basis of inspection conducted on 20-01-2021.
	Decision: Approved. Firm will revise the label claim as per the decision taken by the Board in instant meeting regarding formulation of "Cephradine for Injection" along with submission of requisite fee (if required) for pre-registration correction/changes of label claim as per notification 7-11/2012-B&A/DRAP dated 07.05.2021 and 13.07.2021.	

Case 05; Registration applications of deferred (veterinary) drugs on Form 5.

1891.	Name and address of manufacturer/ Applicant	M/s Zakfas Pharma Pvt Limited, 12 km Bosan Road, Multan.
	Brand Name + Dosage Form + Strength	Fiprozak Spray.
	Composition	Fipronil……..0.29%
	Diary No. Date of R & I & fee	Dy.No.175, 09-10-2015; Rs.20,000/-, 09-10-2015
	Pharmacological Group	Broad- spectrum insecticide
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml, 120ml, 150ml, 200ml, 250ml, 500ml & Decontrolled
	Me-too status	Could not be confirmed
	GMP status	Latest Not provided
	Remarks of the Evaluator PEC-XIII (a)	• Applied label claim is not complete. • Me- too status could not eb confirmed. • GMP status could not be confirmed. • Section is not verified.
	Decision of 297th meeting of registration Board.	Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Label claim. • GMP Status. • Required manufacturing facility.
	Submission by the firm:	• Firm has submitted the following label claim; Fiprozak spray: Each 100 ml contains: Fibronil …….. 0.29gm. Pack sizes of 100ml, 250ml & 500ml. Z.P. Specifications. • Firm has submitted panel inspection report for renewal of DML and grant of additional section dated 15-06-2021 wherein the panel of inspectors recommends the approval of newly upgrade (revised) Bolus section (veterinary) and renewal of drug manufacturing

		License by way of formulation to M/s Zakfas Pharma (Pvt.) Ltd., 12 km Bosan Road, Multan. • Inspection report has also mentioned Spray section (Veterinary) and the firm also provided letter No. F. 6-1/2013-Lic (M-232) dated 29-08-2013 wherein spray section is also mentioned on the said letter. • Firm has also submitted packing details of frontline. However, no details of Reg. No., Active ingredients and their strengths and name of the firm is provided.
	Remarks of the Evaluator PEC-XIII	• Firm has revised their label claim without submission of applicable fee. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 317th meeting of registration Board.	Deferred for following; • Submission of full fee for revision of label claim. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Submission by the firm:	Firm has submitted me too for the applied product as Forontline Spray, Reg. No. 022176. Firm has revised their label claim as per already approved registered product with submission of 30,000/- fee vide slip No. 06675416 dated 17-11-2022. Fiprozak spray: Each 100 ml contains: Fipronil …….. 0.25gm. Innovator's specifications.
	Remarks of the Evaluator PEC-XIII	•
	Decision: Approved with innovator's specifications and following label claim; **Fiprozak spray:** **Each 100 ml contains:** **Fipronil …….. 0.25gm.**	
1892.	Name and address of manufacturer/ Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, AJ&K (Liquid Injection section (Veterinary) General).
	Brand Name+ Dosage Form + Strength	AL-MECTIA LA INJECTION.
	Composition	Each ml Contains: Ivermectin ……..…10mg Clorsulan ……20mg
	Diary No. Date of R & I & fee	Dy. No. 113 dated: 01-01-2021 Rs.20,000/- 01-01-2021.
	Pharmacological Group	Anthelmintic.
	Type of Form.	Form 5.
	Finished product Specification.	Innovator's Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status.	Could not be confirmed.
	GMP status.	Same as above.
	Remarks of the Evaluator PEC XIII.	• Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) along with registration number, brand name and name of firm. • Official monograph of the applied formulation is available in USP.

	Decision of 307th meeting of Registration Board;	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Reply by the firm;	Firm has submitted revised formulation of their formulation and also provided me too for the new/ revised label claim. Zamec Plus Injection, Zakfas Pharmaceuticals, Reg. No. 063578. Revised label claim is as under; Each ml Contains: Ivermectin ……..…10mg Clorsulan ……100mg
	Remarks of the Evaluator PEC XIII.	• Firm has neither submitted revised form 5 nor any fee for revision of label claim of the applied formulation. • Current GMP status of the firm could not be confirmed.
	Decision: Approved with following label claim; **Each ml Contains:** **Ivermectin ……..…10mg** **Clorsulan ……100mg** **Registration letter will be issued after submission of full fee of 30,000/- for correction/pre-approval change in the label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with revised form 5 and current GMP certificate/last inspection report conducted within last three years.**	
1893.	Name and address of manufacturer/ Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, AJ&K (Liquid Injection section (Veterinary) General).
	Brand Name + Dosage Form+ Strength	Melo 10 Injection.
	Composition	Each ml contains: Meloxicam ……. 10%
	Diary No. Date of R & I & fee	Dy. No. 119 dated: 01-01-2021 Rs.20,000/- 01-01-2021.
	Pharmacological Group	NSAID's.
	Type of Form.	Form 5.
	Finished product Specification.	BP Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status.	Could not be confirmed.
	GMP status.	Same as above.
	Remarks of the Evaluator PEC XIII.	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Official monograph of the applied formulation is not available in pharmacopoeias.
	Decision of 307th meeting of Registration Board;	Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Reply by the firm;	Firm has submitted revised formulation of their formulation and also provided me too for the new/ revised label claim. Camrold 10 liquid Injection, Harrolds Pharma AJK, Reg. No. 109003. **Revised label claim is as under;** **Each ml Contains:** **Meloxicam ……. 10mg.**
	Remarks of the Evaluator PEC XIII.	• Firm has neither submitted revised form 5 nor any fee for revision of label claim of the applied formulation. • Current GMP status of the firm could not be confirmed.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm and same fill volume.
	Decision: Deferred for following; • **Submission of full fee of 30,000/- for correction/pre-approval change in the label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with Current GMP certificate/last inspection report conducted within last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm and same fill volume.**	
1894.	Name and address of manufacturer/ Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, AJ& K (Liquid Injection section (Veterinary) General).
	Brand Name + Dosage Form+ Strength	Eter Fenek Injection.
	Composition	Each ml contains: Meloxicam …… 15%
	Diary No. Date of R & I & fee	Dy. No. 120 dated: 01-01-2021 Rs.20,000/- 01-01-2021.
	Pharmacological Group	NSAID's.
	Type of Form.	Form 5.
	Finished product Specification.	BP Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status.	Could not be confirmed.
	GMP status.	Same as above.
	Remarks of the Evaluator PEC XIII	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Official monograph of the applied formulation is not available in pharmacopoeias.
	Decision of 307th meeting of Registration Board;	Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Reply by the firm;	Firm has submitted revised formulation of their formulation and also provided me too for the new/ revised label claim. Elvosol LA Injection, Elko Organization, Reg. No. 063732. Revised label claim is as under; Each ml Contains: Meloxicam ……. 15mg.
	Remarks of the Evaluator PEC XIII.	• Firm has neither submitted revised form 5 nor any fee for revision of label claim of the applied formulation. • Current GMP status of the firm could not be confirmed.
	Decision: Approved with following label claim; **Each ml contains:** **Meloxicam ……. 15mg.** **Registration letter will be issued after submission of full fee of 30,000/- for correction/pre-approval change in the label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with revised Form 5 and current GMP certificate/last inspection report conducted within last three years.**	
1895.	Name and address of manufacturer/ Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, AJ&K (Liquid Injection section (Veterinary) General).
	Brand Name + Dosage Form+ Strength	Fenik Plus Injection.
	Composition	Each ml contains:

		Meloxicam ……. 20%
	Diary No. Date of R & I & fee	Dy. No. 121 dated: 01-01-2021 Rs.20,000/- 01-01-2021.
	Pharmacological Group	NSAID's.
	Type of Form.	Form 5.
	Finished product Specification.	BP Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status.	Could not be confirmed.
	GMP status.	Same as above.
	Remarks of the Evaluator PEC-XIII.	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Official monograph of the applied formulation is not available in pharmacopoeias.
	Decision of 307th meeting of Registration Board;	Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Reply by the firm;	Firm has submitted revised formulation of their formulation and also provided me too for the new/ revised label claim. Camrold 20 liquid Injection, Harrolds Pharma AJK, Reg. No. 109006. Revised label claim is as under; Each ml Contains: Meloxicam ……. 20mg.
	Remarks of the Evaluator PEC XIII.	• Firm has neither submitted revised form 5 nor any fee for revision of label claim of the applied formulation. • Current GMP status of the firm could not be confirmed. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm and same fill volume.
	Decision: Deferred for following; • **Submission of full fee of 30,000/- for correction/pre-approval change in the label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with Current GMP certificate/last inspection report conducted within last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm and same fill volume.**	
1896.	Name and address of manufacturer/ Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, AJ&K (Liquid Injection section (Veterinary) General).
	Brand Name + Dosage Form+ Strength	Hepa plus injection.
	Composition	Each 100ml contains: Phenoxy-2-methyl-Propionic Acid ……10gm.
	Diary No. Date of R & I & fee	Dy. No. 127 dated: 01-01-2021 Rs.20,000/- 01-01-2021.
	Pharmacological Group	Choleretic agent.
	Type of Form.	Form 5.
	Finished product Specification.	Innovator's Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status.	Hepalyte Injection, M/s. Mylab (Pvt.) Ltd., Reg. No. 073915.
	GMP status.	Same as above.
	Remarks of the Evaluator PEC XIII	• Official monograph of the applied formulation is not available in pharmacopoeias.

	Decision of 307th meeting of Registration Board;	Deferred for pharmacological group of the applied formulation.
	Reply by the firm;	Firm has submitted that their product was deferred due to incorrect pharmacological group. They have provided correct pharmacological group as "Liver Tonic"
	Remarks of the Evaluator PEC XIII	• Firm has not submitted any fee for revision of pharmacological group for the applied formulation. • Current GMP status of the firm could not be confirmed.
	Decision: Approved. **Registration letter will be issued after submission of fee of 7500/- for correction/pre-approval change in the label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with revised form 5 and current GMP certificate/last inspection report conducted within last three years.**	
1897.	Name and address of manufacturer/ Applicant	M/s Nawan Laboratories (Pvt.) Ltd., plots No. 136, sector 15, Korangi Industrial Area Karachi (Dry powder sachet section (General) veterinary).
	Brand Name + Dosage Form + Strength	Easy Digest powder.
	Composition	Each 1000gm contains: Propionic Acid Calcium ……..250gm Propionic Acid Sodium ……400gm Acetanilide ……150gm Magnesium Oxide …….125gm Iron II Sulphate ……..0.400mg Zinc Sulphate ……0.100mg Magnesium Sulphate ……...0.200mg Copper Sulphate ……..0.450mg Cobalt Sulphate ……0.400mg Sodium Molybdate ……0.100mg Sodium Chloride ……20gm
	Diary No. Date of R & I & fee	Dy. No 11444 dated 05-03-2019; Rs.20,000/- dated 04-03-2019.
	Pharmacological Group	Appetizing and digestive tonic powder.
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications.
	Pack size & Demanded Price	100gm sachet & decontrolled.
	Approval status of product in Reference Regulatory Authorities	N/A.
	Me-too status	Alvegest powder, Star Laboratories, Reg. No. 008029.
	GMP status	Firm has submitted routine GMP inspection report dated 25-01-2022 wherein it is concluded that keeping in view the attitude of the management towards continuous improvements and current observations their overall GMP compliance is rated as good.
	Remarks of the Evaluator	• Firm was asked to revise their label claim as per their demanded pack size. They revised their label claim as follows; Each 100-gm powder contains; Propionic Acid Calcium ……. 25gm Propionic Acid Sodium ……40gm Acetanilide ……15gm Magnesium Oxide ……12.5gm Iron II Sulphate ……0.040mg Zinc Sulphate ……0.010mg Magnesium Sulphate ……0.020mg Copper Sulphate ……...0.045mg Cobalt Sulphate ……0.040mg Sodium Molybdate ……0.010mg

		Sodium Chloride ……2gm • Firm has submitted me too details as Alvegest powder manufactured by Star Laboratories, Reg. No. 008029. • *However, the composition of the applied formulation is different from the already approved formulation.*
	Decision of 307th meeting of Registration Board;	Deferred for submission evidence of already approved formulation by the Registration Board with brand name, Registration number & manufacturer name. As the composition of the applied formulation is different from submitted me too in concentration of Iron II Sulphate, Zinc, Magnesium Sulphate, Copper Sulphate, Cobalt Sulphate and Sodium Molybdate.
	Reply by the firm;	Firm has revised their formulation as per available approved/registered me too formulation without submission of applicable fee for Change of label claim/formulation. Revised label claim is as under; Each 1000-gm powder contains; Propionic Acid Calcium ……. 250gm Propionic Acid Sodium ……400gm Acetanilide ……150gm Magnesium Oxide ……125gm Iron II Sulphate …… 400mg Zinc Sulphate …… 100mg Magnesium Sulphate ……. 200mg Copper Sulphate ……..... 450mg Cobalt Sulphate ……. 400mg Sodium Molybdate …… 100mg Sodium Chloride …… 20gm
	Remarks of the Evaluator PEC XIII	Full fee along with new form 5 and master formulation shall be submitted.
	Decision: Deferred for following; • **Submission of full fee of 30,000/- for correction/pre-approval change in the label claim, method of manufacture/specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 along with revised form 5 shall be submitted.** • **Evidence of testing facility required for conducting testing of the applied formulation.**	

Agenda of Evaluator PEC-XV.

1898.	Name, address of Applicant / Marketing Authorization Holder	M/s Pasteur & Fleming Pharmaceuticals Pvt. Ltd. Industrial Estate Hattar.
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals (Pvt). Ltd. Plot No. 70-A, Road No. 04, Phase 3, Industrial Estate. Hattar, Khyber Pakhtunkhwa Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No.29637 dated 19/10/2022
	Details of fee submitted	PKR 30,000/-: dated. 02/08/2022. Slip No. 90054196801
	The proposed proprietary name / brand name	Ciflox 250mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin as Hydrochloride (USP)……..…….250mg
	Pharmaceutical form of applied drug	White colored film coated , Oblong shaped, oral tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolone (Broad spectrum Antibiotic)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 250mg Tablets U.K MHRA Accord Health Care Limited Sage .House 319 Pimmer Road Harrow Middlesex.
	For generic drugs (me-too status)	Cipax 250mg Tablet mg by M/s Genome Pharma Reg. No. 062916
	GMP status of the Finished product manufacturer	New license granted on 10/11/2021 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	M/s Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 75 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches # :(00510011/001/2014, 00510011/002/2014, 00510011/003/2014)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Cipvax 250mg Tablets by Genome Pharmaceuticals performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the same brand that is 250mg tablet by Genome Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA				
Manufacturer of API		M/s Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.		
API Lot No.		00510011/280/2021		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-07	T-08	T-09
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		04-2022	04-2022	04-2022
Date of Initiation		08-04-2022	08-04-2022	08-04-2022
No. of Batches		03		
Administrative Portion				
37.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
38.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	DML # 00325. Sami Basic Manufacturer .Copy of GMP certificate No. 129/2020-DRAP (Ad/1998630-530) issued by DRAP.		
39.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice # 2334, Dated .29/03/2022 By Pharmagen Lahore		

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

Remarks OF Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit specification and analytical procedures of drug substance from drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 respectively.	Firm submit the specification and analytical procedure of drug substance in compliance of USP.
2.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.	Firm submitted the analytical verification of drug substance in which the specificity parameter has not performed in accordance with ICH guidelines.
3.	Clarification is required either the drug substance complies USP or BP specifications, since the COA by drug substance manufacturer claimed that the API complies BP specification, while the specification and analytical method reflects that the drug substance comply USP specification. Further, the quality analysis report of drug substance by drug product manufacturer is also required.	Firm submitted the COA of drug substance by both drug substance manufacturer and drug product manufacturer. However, the result of water content test was out of specification in the batch analysis report of drug substance by drug product manufacturer i.e. 3.5% ,while the USP recommended water content between 4.7%-6.7%.
4.	Justify why the pharmaceutical equivalence and comparative dissolution profile studies were conducted against the comparator product instead of using brand leader/innovator product.	Firm submit the revised pharmaceutical equivalence report performed against the novidat tablet of M/s. Sami Pharmaceuticals (Batch no. 228G, Exp date: 11-2024)
5.	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed." Since the submitted one-page document did not fulfill the requirement of this section.	Firm submitted the Comparative Dissolution Profile (CDP) conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2.

6.	Provide compatibility studies of the Drug Substance(s) with excipients as the qualitative composition of the formulation is not similar to innovator / reference product.	Firm replied that we performed 6th months stability study, the product is physically and chemically stable.
7.	Submit verification report of analytical method of the drug product in section 3.2.P.5.3,since the submitted summary table did not fulfill the requirement of this section.	Firm submitted the analytical verification of drug substance in which the specificity parameter has not performed in accordance with ICH guidelines.
8.	Provide certificate of analysis of reference standard /working standard used for testing of the drug product.	Firm submitted the COA of working standard.
9.	Clarification is required on which date stability study has been initiated, as the covering letter of stability data reflects that initiation date was 08-04-2022 while the stability data sheet reflects that the date of analysis of zero month was 14-04-2022.	Firm replied that the date mentioned on the covering letter was mistakenly written ,the actual date is 14/04/2022.
10	Clarification required that the results of assay test represents either the quantity of ciprofloxacin or ciprofloxacin hydrochloride.	Firm claimed that the assay results were the quantification of ciprofloxacin HCl, while the USP monograph recommends the quantification of ciprofloxacin in the assay results.
11	According to the chromatograms of assay testing, retention time of main peak was around 2.6 minutes, while as per USP monograph the retention time for ciprofloxacin is 6.4-10.8minutes justify, the change of RT of applied product from that specified in USP.	Firm replied that we had used the 150mm column instead of 250mm column, due to the change of column specification the peak retention time is reduced. Now we had bought 250mm column, again performed assay test of ciprofloxacin HCl and performed confirmation of assay test and the main peak of said product has arrived in 5.9 minutes.
12	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm replied that we have used Schimadzu HPLC there was a problem in the software of the attached computer system due to this problem the audit trail couldn't be turned on the whole process of stability study.
13	Raw data sheets of assay testing performed during different time points of stability study should be submitted.	Not submitted
14	According to the BMR theoretical weight per tablet is 374 for 250mg tablet /748mg for 500mg tablet, while batch formula given in section 3.2.P.3.1 specified that average weight of tablet would be 394 for 250mg strength /768mgfor 500mg strength, clarity required regarding the disparity in average weight of tablet and provide along with calculations.	Firm has not submitted the calculation of weight per tablet along with adjustment of HCL factor and water content.

Decision: Approved.

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

• **Manufacturer shall dispense drug substance on basis of the actual potency determined during drug substance analysis for commercial manufacturing of drug product.** **Registration letter will be issued upon submission of following:** **i. Pharmaceutical equivalence and Comparative Dissolution Profile(CDP) studies against the innovator's product i.e. Ciproxin tablet.** **ii. Drug substance batch analysis COA as per USP monograph along with analytical method verification studies for drug substance performed by drug product manufacturer.** **iii. Data of next time point of long term stability studies of drug product wherein assay test shall be conducted as per USP monograph along with raw data sheets for submitted stability studies.**		
1899.	Name, / Marketing Authorization Holder address of Applicant	M/s Pasteur & Fleming Pharmaceuticals Pvt. Ltd. Industrial Estate Hattar.
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharmaceuticals (Pvt). Ltd. Plot No. 70-A, Road No. 04, Phase 3, Industrial Estate. Hattar, Khyber Pakhtunkhwa Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.29327 dated 17/10/2022
	Details of fee submitted	PKR 30,000/-: dated. 02/08/2022. Slip No. 90054196801
	The proposed proprietary name / brand name	Ciflox 500mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin as Hydrochloride (USP)……..…….500mg
	Pharmaceutical form of applied drug	White colored film coated , Oblong shaped, oral tablet
	Pharmacotherapeutic Group of (API)	Fluoroquinolone (Broad spectrum Antibiotic)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Cipax 500mg Tablet mg by M/s Genome Pharma Reg. No. 043310
	GMP status of the Finished product manufacturer	New license granted on 10/11/2021 Tablet (General & General Antibiotic) section approved.

	Name and address of API manufacturer.	M/s Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 75 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches # :(00510011/001/2014, 00510011/002/2014, 00510011/003/2014)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Cipvax 500mg Tablets by Genome Pharmaceuticals performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the same brand that is 250mg tablet by Genome Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Pharmagen Limited 34-Km, Ferozepur Road, Lahore, Pakistan.
API Lot No.	00510011/280/2021
Description of Pack	Alu-Alu blister packed in unit carton (1×10's)

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-07	T-08	T-09
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	08-04-2022	08-04-2022	08-04-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	DML # 00325. Sami Basic Manufacturer .Copy of GMP certificate No. 129/2020-DRAP (Ad/1998630-530) issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Invoice # 2334, Dated .29/03/2022 By Pharmagen Lahore
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit specification and analytical procedures of drug substance from drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 respectively.	Firm submit the specification and analytical procedure of drug substance in compliance of USP.
2.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the	Firm submitted the analytical verification of drug substance in which the specificity parameter has not performed in accordance with ICH guidelines.

	testing of drug substance was carried out without performing verification studies.	
3.	Clarification is required either the drug substance complies USP or BP specifications, since the COA by drug substance manufacturer claimed that the API complies BP specification, while the specification and analytical method reflects that the drug substance comply USP specification. Further, the quality analysis report of drug substance by drug product manufacturer is also required.	Firm submitted the COA of drug substance by both drug substance manufacturer and drug product manufacturer. However, the result of water content test was out of specification in the batch analysis report of drug substance by drug product manufacturer i.e. 3.5% ,while the USP recommended water content between 4.7%-6.7%.
4.	Justify why the pharmaceutical equivalence and comparative dissolution profile studies were conducted against the comparator product instead of using brand leader/innovator product.	Firm submit the revised pharmaceutical equivalence report performed against the novidat 500mg tablet of M/s. Sami Pharmaceuticals (Batch no. 228G, Exp date: 11-2024) Both 500mg and 250mg tablet of reference product has same batch no. according to the submitted comparison data.
5.	Submit results of Comparative Dissolution Profile (CDP) in section 3.2.P.2.2.1 to comply the decision of 293rd meeting of Registration Board, which states that "Where applicable the results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2 should be submitted and discussed." Since the submitted one-page document did not fulfill the requirement of this section.	Firm submitted the Comparative Dissolution Profile (CDP) conducted in three BCS media across the physiological pH range along with calculation of similarity factor *f*2.
6.	Provide compatibility studies of the Drug Substance(s) with excipients as the qualitative composition of the formulation is not similar to innovator / reference product.	Firm replied that we performed 6th months stability study, the product is physically and chemically stable.
7.	Submit verification report of analytical method of the drug product in section 3.2.P.5.3,since the submitted summary table did not fulfill the requirement of this section.	Firm submitted the analytical verification of drug substance in which the specificity parameter has not performed in accordance with ICH guidelines.
8.	Provide certificate of analysis of reference standard /working standard used for testing of the drug product.	Firm submitted the COA of working standard.
9.	Clarification is required on which date stability study has been initiated, as the covering letter of stability data reflects that initiation date was 08-04-2022 while the stability data sheet reflects that the date of analysis of zero month was 14-04-2022.	Firm replied that the date mentioned on the covering letter was mistakenly written ,the actual date is 14/04/2022.
10	Clarification required that the results of assay test represents either the quantity of ciprofloxacin or ciprofloxacin hydrochloride.	Firm claimed that the assay results were the quantification of ciprofloxacin HCl, while the USP monograph recommends the quantification of ciprofloxacin in the assay results.
11	According to the chromatograms of assay testing, retention time of main peak was	Firm replied that we had used the 150mm column instead of 250mm column, due to the

	around 2.6 minutes, while as per USP monograph the retention time for ciprofloxacin is 6.4-10.8minutes justify, the change of RT of applied product from that specified in USP.	change of column specification the peak retention time is reduced. Now we had bought 250mm column, again performed assay test of ciprofloxacin HCl and performed confirmation of assay test and the main peak of said product has arrived in 5.9 minutes.
12	Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm replied that we have used Schimadzu HPLC there was a problem in the software of the attached computer system due to this problem the audit trail couldn't be turned on the whole process of stability study.
13	Raw data sheets of assay testing performed during different time points of stability study should be submitted.	Not submitted
14	According to the BMR theoretical weight per tablet is 374 for 250mg tablet /748mg for 500mg tablet, while batch formula given in section 3.2.P.3.1 specified that average weight of tablet would be 394 for 250mg strength /768mgfor 500mg strength, clarity required regarding the disparity in average weight of tablet and provide along with calculations.	Firm has not submitted the calculation of filled weight along with adjustment of HCL factor and water content.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer shall dispense drug substance on basis of the actual potency determined during drug substance analysis for commercial manufacturing of drug product.**

Registration letter will be issued upon submission of following:

i. **Pharmaceutical equivalence and Comparative Dissolution Profile(CDP) studies against the innovator's product i.e. Ciproxin tablet.**
ii. **Drug substance batch analysis COA as per USP monograph along with analytical method verification studies for drug substance performed by drug product manufacturer.**
i. **Data of next time point of long term stability studies of drug product wherein assay test shall be conducted as per USP monograph along with raw data sheets for submitted stability studies.**

1900.	Name, / Marketing Authorization Holder address of Applicant	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.30834 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 17-10-2022
	The proposed proprietary name / brand name	**Mero-F 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem trihydrate equivalent to meropenem …… 500mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	USP Type-II Glass Vial
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved).
	For generic drugs (me-too status)	Meronem Injection by M/s Pfizer, Reg. No. 018543
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem)
	Name and address of API manufacturer.	Kopran Research Laboratories Limited. K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm is submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

		Meropenem Trihydrate is the dried (dried in Agitated Neutsche Filter Drier) sterile powder blended with sodium carbonate in a ratio of 83%:17% to yield meropenem for injection.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MPIV/B1505008, MPIV/B1505009, MPIV/B1505010)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product. Filled weight per vial calculation has been performed using the potency of meropenem on as is basis and according to the calculation the standard filling weight is 705 mg. (Maximum weight: 726mg and minimum weight: 683mg)
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader Meroget Injection by M/s Getz Pharma (Batch # 921 0407003) by performing quality tests (Identification, Assay, pH, Water content etc.).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Kopran Research Laboratories Limited. K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra State, India.		
API Lot No.	MPIV/82111068		
Description of Pack (Container closure system)	Mero-F 500mg Injection is filled in Glass vial USP Type-II further packed in unit carton along with patient leaflet insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	001	001
Batch Size	900 Vial	900 Vial	900 Vial
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	09-03-2022	09-03-2022	09-03-2022
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERTKD/89275/2020/11/33788 issued by FDA Bandra Mumbai valid till 19/10/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. EXP-2122-328 dated 28-12-2021 is submitted for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator: Firm has submitted the analytical instrument list in section 3.2.A.1, from which it is evident that firm has atomic absorption spectrophotometer (Model no. iCE 3000 Series of Thermo Scientific USA.		
Decision: Approved. Firm shall submit Pharmaceutical equivalence studies against the innovator product before issuance of registration letter. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1901.	Name, / Marketing Authorization Holder address of Applicant	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.30833 dated 31/10/2022
	Details of fee submitted	PKR 30,000/-: dated 17-10-2022
	The proposed proprietary name / brand name	**Mero-F 1000mg Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Meropenem trihydrate equivalent to meropenem …… 1000mg (blended with sodium carbonate)
	Pharmaceutical form of applied drug	USP Type-II Glass Vial
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved).
	For generic drugs (me-too status)	Meronem 1g Injection by M/s Pfizer Pakistan Reg.# 018548
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem)
	Name and address of API manufacturer.	Kopran Research Laboratories Limited. K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm is submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Meropenem Trihydrate is the dried (dried in Agitated Neutsche Filter Drier) sterile powder blended with sodium carbonate in a ratio of 83%:17% to yield meropenem for injection.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH for 48 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MPIV/B1505008, MPIV/B1505009, MPIV/B1505010)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product. Filled weight per vial calculation has been performed using the potency of meropenem on as is basis and according to the calculation the standard filling weight is 1410 mg. (Maximum weight: 1452 mg and minimum weight: 1367mg)
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader Meroget Injection by M/s Getz Pharma (Batch # 921 0408004) by performing quality tests (Identification, Assay, pH, Water content etc.).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Kopran Research Laboratories Limited. K-4/4 Additional MIDC, Post Birwadi, TAL. MAHAD, Dist. Raigad, Raigad, 402302, Maharashtra State, India.		
API Lot No.	MPIV/82111068		
Description of Pack (Container closure system)	Mero-F 500mg Injection is filled in Glass vial USP Type-II further packed in unit carton along with patient leaflet insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	727 Vial	727 Vial	727 Vial
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	09-03-2022	09-03-2022	09-03-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERTKD/89275/2020/11/33788 issued by FDA Bandra Mumbai valid till 19/10/2023.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. EXP-2122-328 dated 28-12-2021 is submitted for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator: Firm has submitted the analytical instrument list in section 3.2.A.1, from which it is evident that firm has atomic absorption spectrophotometer (Model no. iCE 3000 Series of Thermo Scientific USA.		
Decision: Approved. Firm shall submit Pharmaceutical equivalence studies against the innovator product before issuance of registration letter. **• Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** **• Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1902.	Name, / Marketing Authorization Holder address of Applicant	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30341 dated 26/10/2022
	Details of fee submitted	PKR 30,000/-: dated 17-10-2022
	The proposed proprietary name / brand name	Fletazo Injection 2.25g
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin (as Piperacillin Sodium) ……. 2g Tazobactam (as Tazobactam Sodium) 0.25g
	Pharmaceutical form of applied drug	USP Type-II Glass Vial
	Pharmacotherapeutic Group of (API)	Antibiotics Penicillin: Broad-spectrum β-lactam antibiotic

		Tazobactam: Beta-lactamase inhibitor
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (ZOSYN 2.25g Injection)
	For generic drugs (me-too status)	Tanzo 2.25g Injection by M/s Bosch Pharmaceutical Pvt. Ltd. Karachi Reg# 039593
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang RdDongjua Town Licheng District, Jinan, Shandong, 25105, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm is submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader Meroget Injection by M/s Bosch Pharmaceuticals Pvt. Ltd.

		(Batch # PN 220030) by performing quality tests (Identification, Assay, pH, Water content etc.).	
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang Rd Dongjua Town Licheng District, Jinan, Shandong, 25105, China.		
API Lot No.	HF1123G5		
Description of Pack (Container closure system)	Fletazo Injection 2.25g is filled in Glass vial USP Type-II further packed in unit carton along with patient leaflet insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	001	001
Batch Size	1415 Vial	1415 Vial	1415 Vial
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	16-04-2022	16-04-2022	16-04-2022
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2020/HPF/PT/004 Eudra GMP dated 17/4/2020.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. XLH/220106-D dated 26-1-2022 is submitted for the purpose of test/analysis and stability studies is granted.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks OF Evaluator:			

<table>
<tr><th>S.no.</th><th>Observations/Deficiencies/ Short-comings</th><th>Response of the Firm</th></tr>
<tr><td>1.</td><td>Justify the composition of applied formulation without EDTA and buffering agent comparing the formulation of USFDA innovator product which contains EDTA as chelating agent and citric acid monohydrate as a buffer.</td><td>Firm replied that “Fletazo Injection (Piperacillin as Sodium and Tazobactam as Sodium) complies all parameters as mentioned in USP monograph.

• USP monograph requires it to indicate its sodium content on label and there is no requirement to mention buffer and stabilizer nor is any testing required for. Hence it was not mentioned in label;
• Our application part 2.3.P.1 and 2.3.P.3.2 contains information about the presence of EDTA i.e 0.5mg for 2.25g injection and 1.0mg of EDTA in 4.5g injection.
We assure the competent authority that the weight of filled vial will be adjusted by incorporating the quantity of EDTA and citric acid during commercial batches.
• Since testing of EDTA and buffering agent was not required, so it was not mentioned in DS manufacturer’s Specifications and COA. As per our supplier, formulation ingredients are not declared in given open part of DMF. EDTA and citric acid are mixed before Lyophilisation.
• Low pH leads to inactivation of drug so USP monograph specify pH limits and our results are well within limit, tabulated below:
<table><tr><th>Batch #</th><th>USP limit</th><th>Fletazo Injection 2.25g</th><th>Fletazo Injection 4.5g</th></tr><tr><td>T-001</td><td rowspan="3">5.0 – 7.0</td><td>6.05</td><td>6.12</td></tr><tr><td>T-002</td><td>6.16</td><td>6.01</td></tr><tr><td>T-003</td><td>6.17</td><td>6.15</td></tr></table>
• Our product Fletazo Injection, results complies the USP limits for PARTICULATE MATTER IN INJECTIONS <788>, tabulated below. Presence of EDTA lessen the possibility of particulate matter accumulation upon reconstitution.
<table><tr><th rowspan="2">Batch #</th><th rowspan="2">USP limit</th><th colspan="2">*Fletazo Injection 2.25g</th><th colspan="2">*Fletazo Injection 4.5g</th></tr><tr><th>10 µm</th><th>25 µm</th><th>10 µm</th><th>25 µm</th></tr><tr><td>T-001</td><td rowspan="3">≥ 10µm NMT 1200 particle/gm</td><td>50</td><td>4</td><td>80</td><td>7</td></tr><tr><td>T-002</td><td>42</td><td>1</td><td>51</td><td>6</td></tr><tr><td>T-003</td><td>53</td><td>0</td><td>56</td><td>2</td></tr></table>*Slips are attached.
Moreover, pharmaceutical equivalence and stability study also shows satisfactory results as per USP monograph.</td></tr>
<tr><td>2.</td><td>Submit documents for the procurement of API including</td><td>DRAP attested commercial invoice submitted by the firm with the following details:</td></tr>
</table>

	copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Commercial invoice number: XLH 220106-D dated Jan 26 2022 Batch/Lot # HF 1123G5 Manufacturing date: 25/10/2021 Expiry date: 24/10/2024
3.	Justify the filled weight of powder per vial against the determined potency of drug on as is basis.	Firm replied that Ratio of Piperacillin & Tazobactam in our product applied = 8:1 Raw Material imported is mixture of Piperacillin & Tazobactam having ratio of assay (8:1) Assay of Piperacillin = 83.72% Assay of Tazobactam = 10.24 % Ratio of Assay =83.72/10.24 = 8:1 Factor of Piperacillin = 1.042 Factor of Tazobactam =1.073 Potency adjustment = filled weight / assay x 100 We assure the competent authority that the filled weight of powder per vial will be adjusted against the determined potency and by incorporating the quantity of EDTA and citric acid during commercial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer shall dispense drug substance on basis of the actual potency determined during drug substance analysis for commercial manufacturing of drug product.**

1903.	Name, / Marketing Authorization Holder address of Applicant	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30582 dated 28/10/2022
	Details of fee submitted	PKR 30,000/-: dated 17-10-2022
	The proposed proprietary name / brand name	Fletazo Injection 4.5g

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Piperacillin (as Piperacillin Sodium) ……. 4g Tazobactam (as Tazobactam Sodium) 0.5g
	Pharmaceutical form of applied drug	USP Type-II Glass Vial
	Pharmacotherapeutic Group of (API)	Antibiotics Penicillin: Broad-spectrum β-lactam antibiotic Tazobactam: Beta-lactamase inhibitor
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in FDA (ZOSYN 4.5g Injection)
	For generic drugs (me-too status)	Tanzo 4.5g Injection by M/s Bosch Pharmaceutical Pvt. Ltd. Karachi
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021. Following sections have been granted by CLB: Oral dry powder for suspension(penicillin),Capsule(penicillin),tablet (penicillin),Dry powder Injectable (penicillin),Dry powder injectable (Carbapenem.
	Name and address of API manufacturer.	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang Rd Dongjua Town Licheng District, Jinan, Shandong, 25105, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm is submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.	
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader Meroget Injection by M/s Bosch Pharmaceuticals Pvt. Ltd. (Batch # PN 220071) by performing quality tests (Identification, Assay, pH, Water content etc.).	
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.	
STABILITY STUDY DATA			
Manufacturer of API	Shandong Anxin Pharmaceutical Co. Limited. Address: 106878 Wenliang Rd Dongjua Town Licheng District, Jinan, Shandong, 25105, China.		
API Lot No.	HF1123G5		
Description of Pack (Container closure system)	Fletazo Injection 4.5g is filled in Glass vial USP Type-II further packed in unit carton along with patient leaflet insert		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	001	001	001
Batch Size	1415 Vial	1415 Vial	1415 Vial
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	16-04-2022	16-04-2022	16-04-2022
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML Granted.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2020/HPF/PT/004 Eudra GMP dated 17/4/2020.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. XLH/220106-D dated 26-1-2022 is submitted for the purpose of test/analysis and stability studies is granted.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	

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

Remarks OF Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify the composition of applied formulation without EDTA and buffering agent comparing the formulation of USFDA innovator product which contains EDTA as chelating agent and citric acid monohydrate as a buffer.	Firm replied that "Fletazo Injection (Piperacillin as Sodium and Tazobactam as Sodium) complies all parameters as mentioned in USP monograph. • USP monograph requires it to indicate its sodium content on label and there is no requirement to mention buffer and stabilizer nor is any testing required for. Hence it was not mentioned in label; • Our application part 2.3.P.1 and 2.3.P.3.2 contains information about the presence of EDTA i.e 0.5mg for 2.25g injection and 1.0mg of EDTA in 4.5g injection. We assure the competent authority that the weight of filled vial will be adjusted by incorporating the quantity of EDTA and citric acid during commercial batches. • Since testing of EDTA and buffering agent was not required, so it was not mentioned in DS manufacturer's Specifications and COA. As per our supplier, formulation ingredients are not declared in given open part of DMF. EDTA and citric acid are mixed before Lyophilization. • Low pH leads to inactivation of drug so USP monograph specify pH limits and our results are well within limit, tabulated below:

Batch #	USP limit	Fletazo Injection 2.25g	Fletazo Injection 4.5g
T-001	5.0 – 7.0	6.05	6.12
T-002		6.16	6.01
T-003		6.17	6.15

	• Our product Fletazo Injection, results complies the USP limits for PARTICULATE MATTER IN INJECTIONS <788>, tabulated below. Presence of EDTA lessen the possibility of particulate matter accumulation upon reconstitution.

		<table><tr><th rowspan="2">Batch #</th><th rowspan="2">USP limit</th><th colspan="2">*Fletazo Injection 2.25g</th><th colspan="2">*Fletazo Injection 4.5g</th></tr><tr><th>10 µm</th><th>25 µm</th><th>10 µm</th><th>25 µm</th></tr><tr><td>T-001</td><td rowspan="3">≥ 10µm NMT 1200 particle/gm ≥ 25µm NMT 120 particle/gm</td><td>50</td><td>4</td><td>80</td><td>7</td></tr><tr><td>T-002</td><td>42</td><td>1</td><td>51</td><td>6</td></tr><tr><td>T-003</td><td>53</td><td>0</td><td>56</td><td>2</td></tr></table>*Slips are attached. Moreover, pharmaceutical equivalence and stability study also shows satisfactory results as per USP monograph.
2.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	DRAP attested commercial invoice submitted by the firm with the following details: Commercial invoice number: XLH 220106-D dated Jan 26 2022 Batch/Lot # HF 1123G5 Manufacturing date: 25/10/2021 Expiry date: 24/10/2024
3.	Justify the filled weight of powder per vial against the determined potency of drug on as is basis.	Firm replied that Ratio of Piperacillin & Tazobactam in our product applied = 8:1 Raw Material imported is mixture of Piperacillin & Tazobactam having ratio of assay (8:1) Assay of Piperacillin = 83.72% Assay of Tazobactam = 10.24 % Ratio of Assay =83.72/10.24 = 8:1 Factor of Piperacillin = 1.042 Factor of Tazobactam =1.073 Potency adjustment = filled weight / assay x 100 We assure the competent authority that the filled weight of powder per vial will be adjusted against the determined potency and by incorporating the quantity of EDTA and citric acid during commercial batches.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Manufacturer shall dispense drug substance on basis of the actual potency determined during drug substance analysis for commercial manufacturing of drug product.**

Cases of New Sections received on Form 5-F

- M/s Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore

The Central Licensing Board in its 277th meeting held on 15 & 16th October, 2020 has considered and approved the grant of additional section of "Dry Powder Inhaler Capsule section (Steroid)" to M/s Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore

1904.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28770 dated 11-10-2022
	Details of fee submitted	PKR 30,000/-: Deposit Slip # 08904298379
	The proposed proprietary name / brand name	**Covair 150mcg/160mcg Rotacaps**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Indacaterol (as acetate) ……150 mcg Mometasone furoate……. 160 mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains: Indacaterol (as acetate) ……125 mcg Mometasone furoate……. 127.5 mcg
	Pharmaceutical form of applied drug	DPI Capsule (White color powder filled in capsule shell no 3, having grey opaque cap and transparent body.)
	Pharmacotherapeutic Group of (API)	Cholinergic Antagonist: This medicinal product is a combination of indacaterol, a long-acting beta2-adrenergic agonist (LABA), and mometasone furoate, an inhaled synthetic corticosteroid (ICS).
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Atectura® Breezhaler® 125 micrograms/127.5 micrograms inhalation powder, hard capsules (MHRA approved)
	For generic drugs (me-too status)	Atectura Breezhaler inhalation powder, hard capsule 150/160mcg by M/s. Novartis Pharma, Pakistan Approved in 316th DRB meeting

	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 06/2022-DRAP (AD-334240006) issued by DRAP valid till 11/11/2023.
	Name and address of API manufacturer.	Indacaterol Acetate: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate: M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Mometasone furoate is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Whereas Indacaterol acetate complies Manufacturer's specifications. So, firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance as per inhouse specifications.
	Stability studies	Stability study conditions: 1. Indacaterol acetate: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH 2. Mometasone furoate: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Atectura® Breezhaler® 125 micrograms/127.5 micrograms inhalation powder, hard capsules by Novartis Pharmaceuticals UK by performing tests (DUSA (Delivered dose uniformity by dosage sampling apparatus), ACI (Aerodynamic particle size distribution by Andersen cascade impactor (USP Apparatus 3). CDP is not applicable in case of Dry powder inhalers.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Complete description and specification of delivery device describe orange and white body with transparent cavity inhaler device properly sealed packed polythene and suitable to open shell size 3 with smooth opening and closing of device

STABILITY STUDY DATA			
Manufacturer of API	Indacaterol Acetate: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate: M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.		
API Lot No.	Indacaterol acetate: ICA/08/21 Mometasone Furoate: MF-20023 (JM-01)-001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3 x 10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21252	RD-21253	RD-21254
Batch Size	24,000 capsules	24,000 capsules	24,000 capsules
Manufacturing Date	18-01-2022	18-01-2022	18-01-2022

Date of Initiation		01-03-2022	01-03-2022	01-03-2022
No. of Batches		03		
1905.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore		
	Name, address of Manufacturing site.	Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore		
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)		
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)		
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales		
	Dy. No. and date of submission	Dy.No 27450 dated 28-09-202		
	Details of fee submitted	Rs.30,000/- dated 19-09-2022		
	The proposed proprietary name / brand name	**Covair 150mcg/320mcg Rotacaps**		
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Indacaterol (as acetate) ……150 mcg Mometasone furoate……. 320 mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains: Indacaterol (as acetate) ……125 mcg Mometasone furoate……. 260 mcg		
	Pharmaceutical form of applied drug	DPI Capsule (White color powder filled in capsule shell no 3, having purple opaque cap and transparent body.)		
	Pharmacotherapeutic Group of (API)	Cholinergic Antagonist: This medicinal product is a combination of indacaterol, a long-acting beta2-adrenergic agonist (LABA), and mometasone furoate, an inhaled synthetic corticosteroid (ICS).		
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator		
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's		
	Proposed unit price	As per SRO		
	The status in reference regulatory authorities	Bemrist Breezhaler 125 micrograms/260 micrograms inhalation powder, hard capsules (MHRA approved)		
	For generic drugs (me-too status)	Atectura Breezhaler inhalation powder, hard capsule 150/320mcg by M/s. Novartis Pharma, Pakistan Approved in 316th DRB meeting		
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 06/2022-DRAP (AD-334240006) issued by DRAP valid till 11/11/2023.		

	Name and address of API manufacturer.	Indacaterol Acetate: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate: M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Mometasone furoate is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Whereas Indacaterol acetate complies Manufacturer's specifications. So, firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance as per inhouse specifications.
	Stability studies	Stability study conditions: 3. Indacaterol acetate: Real time: 30°C ± 2°C / 65% ± 5%RH for 9 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ICA/01/21, ICA/01/21, ICA/01/21) 4. Mometasone furoate:

		Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (MF-10002(JM-01)001, MF-10003(JM-01)001, MF-10004(JM-01)001)
	Module-III (Drug Produ ct):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Bemrist Breezhaler 125 micrograms/260 micrograms inhalation powder, hard capsules by Novartis Pharmaceuticals UK by performing tests (DUSA (Delivered dose uniformity by dosage sampling apparatus), ACI (Aerodynamic particle size distribution by Andersen cascade impactor (USP Apparatus 3). CDP is not applicable in case of Dry powder inhalers.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Complete description and specification of delivery device describe orange and white body with transparent cavity inhaler device properly sealed packed polythene and suitable to open shell size 3 with smooth opening and closing of device

STABILITY STUDY DATA	
Manufacturer of API	Indacaterol Acetate: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate: M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.
API Lot No.	Indacaterol Acetate: ICA/08/21 Mometasone Furoate: MF-20023 (JM-01)-001

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3 x 10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21255	RD-21256	RD-21257
Batch Size	24,000 capsules	24,000 capsules	24,000 capsules
Manufacturing Date	19-01-2022	19-01-2022	19-01-2022
Date of Initiation	01-03-2022	01-03-2022	01-03-2022
No. of Batches	03		

1906.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27449 dated 28-09-2022
	Details of fee submitted	Rs.30,000/- dated 20-09-2022
	The proposed proprietary name / brand name	**Covair 150mcg/80mcg Rotacaps**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Indacaterol (as acetate) ……150 mcg Mometasone furoate……. 80 mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains: Indacaterol (as acetate) ……125 mcg Mometasone furoate……. 62.5 mcg
	Pharmaceutical form of applied drug	DPI Capsule (White color powder filled in capsule shell no 3, having yellowish green cap and transparent body.)
	Pharmacotherapeutic Group of (API)	Cholinergic Antagonist: This medicinal product is a combination of indacaterol, a long-acting beta2-adrenergic agonist (LABA), and mometasone furoate, an inhaled synthetic corticosteroid (ICS).
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator

	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bemrist Breezhaler 125 micrograms/62.5 micrograms inhalation powder, hard capsules. (MHRA approved)
	For generic drugs (me-too status)	--
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 06/2022-DRAP (AD-334240006) issued by DRAP valid till 11/11/2023.
	Name and address of API manufacturer.	Indacaterol Acetate: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate: M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Mometasone furoate is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Whereas Indacaterol acetate complies Manufacturer's specifications. So, firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance as per inhouse specifications.
	Stability studies	Stability study conditions: 5. Indacaterol acetate: Real time: 30°C ± 2°C / 65% ± 5%RH for 9 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ICA/01/21, ICA/01/21, ICA/01/21) 6. Mometasone furoate: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (MF-10002(JM-01)001, MF-10003(JM-01)001, MF-10004(JM-01)001)
	Module-III (Drug Produ ct):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Bemrist Breezhaler 125 micrograms/62.5 micrograms inhalation powder, hard capsules by Novartis Pharmaceuticals UK by performing tests (DUSA (Delivered dose uniformity by dosage sampling apparatus), ACI (Aerodynamic particle size distribution by Andersen cascade impactor (USP Apparatus 3). CDP is not applicable in case of Dry powder inhalers.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Complete description and specification of delivery device describe orange and white body with transparent cavity inhaler device properly sealed packed polythene and suitable to open shell size 3 with smooth opening and closing of device

STABILITY STUDY DATA	
Manufacturer of API	Indacaterol Acetate: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate:

	M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.		
API Lot No.	Indacaterol Acetate: ICA/08/21 Mometasone Furoate: MF-20023 (JM-01)-001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3 x 10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21249	RD-21250	RD-21251
Batch Size	24,000 capsules	24,000 capsules	24,000 capsules
Manufacturing Date	17-01-2022	17-01-2022	17-01-2022
Date of Initiation	08-02-2022	08-02-2022	08-02-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to previous approval of Ultivair 50mcg/ 110mcg rotacaps, which was presented in 320th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	M/s Aarti Industries Limited: Copy of License no. 28-KD/433 issued by FDA Maharashtra valid till 16-08-2026. M/s Melody Helathcare: Copy of License no. 25KD/649 issued by FDA Maharashtra valid till 24-05-2027.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Indacaterol Acetate: Firm has submitted copy of invoice (invoice# MBR2122/GEP00034) Dated 23-7-2021 cleared by DRAP Lahore office dated 03-08-2021 specifying import 80gm of Indacaterol Acetate (Batch# ICA/08/21). Mometasone Furoate: Firm has submitted copy of invoice (invoice# EX/7483/20-21) Dated 20-3-2021 cleared by DRAP Lahore office dated 05-4-2021 specifying import 120gm Mometasone Furoate (Batch# MF-20023 (JM-01)-001).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Section#	Observations	Firm's response

1.1	Submit evidence of generic / me-too status alongwith registration number, brand name and name of firm or else submit differential fee of Rs. 45,000/- for each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Differential fee of Rs. 45,000/ for each strength against challan no: 48731624, 337526673 and 04557284157 has been submitted dated 23-11-2022.
3.2.S.4 (Indacaterol)	• Clarification shall be submitted regarding polymorphic form of Indacaterol. • Qualification date of the working standard has been reported as June 2022, whereas the drug substance analysis has been conducted prior to this date. • Long term stability studies data has been submitted for 9 months only.	• Polymorphic form of Indacaterol acetate is crystalline form as single R-Isomer and same is depicted in general properties and elucidation of characterization of substance along with reports of XPRD analysis. • Qualification date of the working standard that has been utilized during drug substance analysis is November-2021. • Whereas the working standard having qualification date June-2022 was used for further analysis. • Firm has submitted long term stability studies till 18 months as per Zone IVA, from drug substance manufacturer.
3.2.S.4 (Mometasone)	Drug substance specifications shall include test of specific optical rotation.	Firm has submitted drug substance specifications including test of specific optical rotation and has also referred to submitted COA , wherein test of specific optical rotation was performed.
3.2.P.1	Details of accompanying device shall be submitted.	Medical device name: Rotaflo Model Number: DL-D07 Specification attached as Annexure-VI The same device is already approved and used with our registered product Glynvair 50mcg/110mcg Rotacaps having registration number 113986 dated 27th October 2022.
3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests for both applied and reference formulation.	Firm has submitted Pharmaceutical equivalence report against the innovator product of "Atectura breezhaler" for each strength wherein performance of various tests including "Assay", "Delivered Dose Uniformity" & Aerodynamic particle size distribution has been reported.
3.2.P.5.1	• Justification shall be submitted for not including test of "Indacaterol S-enantiomer" in drug product specifications. • Justification shall be submitted for the limits of Assay test.	• Test of' Indacaterol S- Enantiomer' has been included and controlled at stage of API analysis. • The Assay limits set due to micro-contents of active substance in the formulation, and as per generalized DPI's assay limit available in the British Pharmacopeia. Therefore, the same limit of Assay test has been used to ensure the delivery dose of product.

Decision: Registration Board approved the applications of "Covair 150mcg/160mcg Rotacaps", "Covair 150mcg/320mcg Rotacaps" & "Covair 150mcg/80mcg Rotacaps".

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

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

Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter: "**Rotaflo (inhaler Device) Model Number: DL-D07."**		
1907.	Name address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited of 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27451 dated 28-09-2022
	Details of fee submitted	PKR 75,000/-: Deposit Slip # 08904298379
	The proposed proprietary name / brand name	Glyvair 50mcg/ 150mcg/ 160mcg Rotacaps
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Indacaterol (as acetate) ……150mcg Glycopyrronium (as Bromide) …50mcg Mometasone Furoate……160mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains: Indacaterol (as acetate) ……114mcg Glycopyrronium (as Bromide) …46mcg Mometasone Furoate……136mcg
	Pharmaceutical form of applied drug	DPI Capsule (White color powder filled in capsule shell no 3, having blue transparent cap and transparent body.)
	Pharmacotherapeutic Group of (API)	Cholinergic Antagonist: This medicinal product is a combination of indacaterol, a long-acting beta2-adrenergic agonist (LABA), glycopyrronium, a long-acting muscarinic receptor antagonist (LAMA) and mometasone furoate, an inhaled synthetic corticosteroid (ICS).
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Enerzair Breezhaler 114 Micrograms/46 Micrograms/136 Micrograms Inhalation Powder Hard Capsules (MHRA approved)
	For generic drugs (me-too status)	Enerzair Breezhaler Inhalation Powder Hard Capsule 150/50/160mcg by M/s. Novartis Pharma, Pakistan Approved in 316th DRB meeting

	GMP status of the Finished product manufacturer	Copy of GMP certificate No. 06/2022-DRAP (AD-334240006) issued by DRAP valid till 11/11/2023.
	Name and address of API manufacturer.	Indacaterol Acetate and Glycopyrronium Bromide: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate: M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Glycopyrronium bromide and Mometasone furoate is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Whereas Indacaterol acetate complies Manufacturer's specifications. So, firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance as per in house specifications.
	Stability studies	Stability study conditions: 1. Glycopyrronium bromide: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

		Batches: (GLY/20003M1, GLY/20004M1, GLY/20005M1) 2. Indacaterol acetate: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 9 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ICA/01/21, ICA/01/21, ICA/01/21) 3. Mometasone furoate: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MF-10002(JM-01)001, MF-10003(JM-01)001, MF-10004(JM-01)001)
	Module-III (Drug Produ ct):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Enerzair Breezhaler 114 Micrograms/46 Micrograms/136 Micrograms Inhalation Powder Hard Capsules by Novartis Pharmaceuticals UK by performing tests (DUSA (Delivered dose uniformity by dosage sampling apparatus), ACI (Aerodynamic particle size distribution by Andersen cascade impactor (USP Apparatus 3). CDP is not applicable in case of Dry powder inhalers.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	Indacaterol Acetate and Glycopyrronium Bromide: M/s MELODY HEALTHCARE PVT. LTD. Plot No. J-73, MIDC, Tarapur, Boisar Dist. Palghar – 401 506, Maharashtra, India. Mometasone Furoate: M/s AARTI INDUSTRIES LIMITED. Unit – IV, Plot No E – 50, MIDC, Tarapur, Taluka & District-Palghar, Pin 401 506 Maharashtra, INDIA.
API Lot No.	Glycopyrronium Bromide: GLY/21001M1 Indacaterol Acetate: ICA/08/21 Mometasone Furoate: MF-20023 (JM-01)-001

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3 x 10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21246	Batch No.	RD-21246
Batch Size	24,000 capsules	Batch Size	24,000 capsules
Manufacturing Date	05-01-2022	Manufacturing Date	05-01-2022
Date of Initiation	01-03-2022	Date of Initiation	01-03-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to previous approval of Ultivair 50mcg/ 110mcg rotacaps, which was presented in 320th meeting of Registration Board.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/ CERT/KD/91716/2020/11/31377 issued by WHO valid till 19/03/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Indacaterol Acetate: Firm has submitted copy of invoice (invoice# MBR2122/GEP00034) Dated 23-7-2021 cleared by DRAP Lahore office dated 03-08-2021 specifying import 80gm of Indacaterol Acetate (Batch# ICA/08/21). Mometasone Furoate: Firm has submitted copy of invoice (invoice# EX/7483/20-21) Dated 20-3-2021 cleared by DRAP Lahore office dated 05-4-2021 specifying import 120gm Mometasone Furoate (Batch# MF-20023 (JM-01)-001). Glycopyrronium bromide: Firm has submitted copy of invoice (invoice# MBR2122/GEB00054) Dated 12-10-2021 cleared by DRAP Lahore office dated 08-11-2021 specifying import 30gm Glycopyrronium bromide (Batch# GLY/21001M1).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Section# Observations Firm's response

1.1	Submit evidence of generic / me-too status alongwith registration number, brand name and name of firm or else submit differential fee of Rs. 45,000/- for each strength as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Differential fee of Rs. 45,000/ for each strength against challan no: 48731624, 337526673 and 04557284157 has been submitted dated 23-11-2022.
3.2.S.4 (Indacaterol)	• Clarification shall be submitted regarding polymorphic form of Indacaterol. • Qualification date of the working standard has been reported as June 2022, whereas the drug substance analysis has been conducted prior to this date. • Long term stability studies data has been submitted for 9 months only.	• Polymorphic form of Indacaterol acetate is crystalline form as single R-Isomer and same is depicted in general properties and elucidation of characterization of substance along with reports of XPRD analysis. • Qualification date of the working standard that has been utilized during drug substance analysis is November-2021. • Whereas the working standard having qualification date June-2022 was used for further analysis. • Firm has submitted long term stability studies till 18 months as per Zone IVA, from drug substance manufacturer.
3.2.S.4 (Mometasone)	Drug substance specifications shall include test of specific optical rotation.	Firm has submitted drug substance specifications including test of specific optical rotation and has also referred to submitted COA , wherein test of specific optical rotation was performed.
3.2.P.1	Details of accompanying device shall be submitted.	Medical device name: Rotaflo Model Number: DL-D07 Specification attached as Annexure-VI The same device is already approved and used with our registered product Glynvair 50mcg/110mcg Rotacaps having registration number 113986 dated 27th October 2022.
3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests for both applied and reference formulation.	Firm has submitted Pharmaceutical equivalence report against the innovator product of "Enerzair breezhaler" for each strength wherein performance of various tests including "Assay", "Delivered Dose Uniformity" & Aerodynamic particle size distribution has been reported.
3.2.P.5.1	• Justification shall be submitted for not including test of "Indacaterol S-enantiomer" in drug product specifications. • Justification shall be submitted for the limits of Assay test.	• Test of' Indacaterol S- Enantiomer' has been included and controlled at stage of API analysis. • The Assay limits set due to micro-contents of active substance in the formulation, and as per generalized DPI's assay limit available in the British Pharmacopeia. Therefore, the same limit of Assay test has been used to ensure the delivery dose of product.

Decision: Approved.

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

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

Registration Board further decided that following details of "Accompanyiing Delivery device" shall be declared on registration letter: "**Rotaflo (inhaler Device) Model Number: DL-D07."**		
1908.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited Lahore
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Lahore Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.23136 dated 16/08/2022
	Details of fee submitted	PKR 30,000/-: dated 27/05/2022
	The proposed proprietary name / brand name	Citi-Pime Injection IV/IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL and Arginine Eq. to Cefepime 2g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 2g by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Maxum Injection 2g (Reg.no. 090510) of M/s. Curexa Health (Pvt.) Ltd. Plot No. 517, Sunder Industrial Estate, Lahore
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	Official monograph of Cefepime HCL and Arginine Eq. to Cefepime is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH CEIV/IB1203011 36 MONTH CEIV/IB1203012 12 MONTH CEIV/IB1203013 Not submitted Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: CEIV/IB1203011/ CEIV/IB1203012/ CEIV/IB1203013
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Maxum Injection 2g by Highnoon pharmaceuticals performing quality tests (Identification, pH , Assay, Constituted Solution, Uniformity of dosage form,sterility,BET).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Ltd India		
API Lot No.	CFM-2104004		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocaine along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Cef-P-001 (on covering page)	Cef-P-001 (on covering page)	Cef-P-001 (on covering page)

		TC008-01 (on stability data sheet) TC006 (on audit trail report)	TC008-01 (on stability data sheet) TC006 (on audit trail report)	TC008-01 (on stability data sheet) TC006 (on audit trail report)
Batch Size		1000 Vials	1000 Vials	1000 Vials
Manufacturing Date		09-2021	09-2021	09-2021
Date of Initiation		26-09-2021	26-09-2021	26-09-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Evaluator:

Deficiencies/ Short-comings

- Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.
- Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"
- Submit complete long-term stability data of all three batches of drug substance, complete data of batch no. CEIV/B1203011 has only been submitted in section 3.2. S.7.
- Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".
- Justify why pharmaceutical equivalence was performed against comparator product instead of using innovator / reference product.
- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting of Registration Board, which states that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided". Since the submitted flow diagram of manufacturing procedure is of different drug product (cefotaxime sodium) instead of cefepime.

- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"
- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.
- Analytical method of drug product verified in section 3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.
- Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the stability data, stability study has performed in the year 2022 whereas the submitted chromatograms and audit trail reports were of 2021, clarification required in this regard.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
- In-use stability studies of reconstituted injection are required along with proposed in-use storage statement and in-use shelf-life.
- Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Decision: Deferred for submission of reply of above-cited shortcomings within six month.

1909.	Name, / Marketing Authorization Holder address of Applicant	M/s PDH Laboratories (Pvt) Ltd. 9.5km Sheikhupura Road Lahore
	Name, address of Manufacturing site.	M/s PDH Laboratories (Pvt) Ltd. 9.5km Sheikhupura Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27641 dated 29/09/2022
	Details of fee submitted	PKR 30,000/-: dated 05/04/2022

	The proposed proprietary name / brand name	**Pd-One Oral Solution 30ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Risperidone….1mg
	Pharmaceutical form of applied drug	Clear colorless solution
	Pharmacotherapeutic Group of (API)	Atypical antipsychotic
	Reference to Finished product specifications	Manufacturer's Specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Risperidone 1mg/5ml by Sandoz a Novartis division in UK (emc)
	For generic drugs (me-too status)	RISP Oral Solution 1mg/ml Adamjee Pharmaceuticals (Pvt.) Ltd. Reg #032219
	GMP status of the Finished product manufacturer	New GMP license was granted on 27/07/2022. New additional section for oral liquid syrup (General) was approved on June 7,2022.
	Name and address of API manufacturer.	Kopalle Pharma Chemicals Private Limited. D133,130,127,124, Road No. 43, Phase 3, Industrial Development Area, Jeedimetla Hyderabad, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Risperidone present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months Batches:(RS-10010415, RS-10021115, RS 10031215)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is RISP Oral Solution 1mg/ml by M/s Adamjee Pharmaceuticals (Pvt.) Ltd by performing quality tests (Identification, Assay, pH). Comparative dissolution profile of syrup is not applicable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Kopalle Pharma Chemicals Private Limited. D133,130,127,124, Road No. 43,Phase 3, Industrial Development Area,Jeedimetla Hyderabad, India.		
API Lot No.	RS-10071120		
Description of Pack (Container closure system)	Clear colorless solution filled in a ambered glass bottle sealed with aluminium cap packed in a unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	28/10/2021	29/10/2021	30/10/2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 49083/TS/2020 issued.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.5201/2020/DRAP-AD-CD(I&E) dated 16/04/2020 is submitted wherein the permission to import different APIs including Risperidone for the purpose of test/analysis and stability studies is granted. Invoice with the title of AURORE Life Sciences,Madhapur,Hyderabad,Telangana

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

Remarks OF Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.	Firm replied that "There was a typo error only in Form 5-F (attached in start of the dossier), rest of the dossier is on USP specifications. It is now corrected and attached." Firm submit the correct specification without fee.
2.	Submit data in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.	Firm has submitted the Analytical procedure and specifications by both Drug substance & Drug Product manufacturer with the claim of BP specifications.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.	Submitted
4.	Justify for not performing all the quality test which are include in USP monograph while establishing the pharmaceutical equivalence with comparator product.	Revised pharmaceutical equivalence report performed against comparator product of M/s. Adamjee RISP Oral Solution 30ml Batch no. 111 expiry date: 01-2024.
5.	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that the applied formulation is composed of iron polymaltose, sorbitol and sugar, clarify the composition of applied oral solution given in manufacturing process development section comparing to the formulation submitted mentioned in section 3.2. P.1.	Firm replied that it was a typographical revised and correct manufacturing method has been submitted.

6.	Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph.	submitted
7.	There were 2 main peaks appeared on most of the chromatograms of analytical method verification report, please, clarify that which of the peak represents the elution of risperidone and identity of other peak.	Firm replied that Revised analytical method verification report will be submitted.
8.	Justify for not performing the test of deliverable volume, microbial enumeration test and test for specified microorganism, since these test are included in the USP monograph of risperidone oral solution.	Revised COAs of three trial batches are submitted by the firm.
9.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Submitted.
10	• As per the analytical method verification report the peak area of chromatograms for the standard solution was 9353890.6940, while as per your stability records the peak area of the standard solution having the same concentration is 2149164.23. Justification is required in this regard how such difference in the area of HPLC can exist using the same method and parameters. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study.	Firm replied that due to new staff, the column of HPLC was not appropriate. We will submit the revised analytical method verification. Without any clarification that which chromatograms are in accordance with the assay method used for the analysis of drug product. Later, firm submitted the revised analytical verification report of drug product dated 8th December, 2022 , which is performed in conformance to the chromatographic recommended by the USP monograph of Risperidone oral, further the chromatograms of verification studies are correlated with the chromatograms of assay testing performed for the stability studies of drug product specifically with reference to the peak area.
11	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3, since you have submitted only the BMR of T-006.	Submitted.

Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 7,500/- for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 13-07-2021.

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

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

- M/s. Winbrains Research Laboratories Plot no.69/1 Block B, Phase I-II, Industrial Estate, Hattar

The Central Licensing Board in its 282nd meeting held on 31st August, 2021 has considered and approved the grant of additional section of "Dry Powder Inhaler Capsule section (General)" to M/s. Winbrains Research Laboratories Plot no.69/1 Block B, Phase I-II, Industrial Estate, Hattar.

1910.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan

	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32464 dated 11/11/2022
	Details of fee submitted	PKR 30,000/-:dated 19/10/2022
	The proposed proprietary name / brand name	Flutimet 100/50mcg RotaCapsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluticasone Propionate……100mcg Salmeterol Xinafoate ……50mcg
	Pharmaceutical form of applied drug	White to off white color powder filled in hard gelatin capsule shells
	Pharmacotherapeutic Group of (API)	Long Acting- Beta agonists Corticosteroids
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved ADVAIR DISKUS 100/50
	For generic drugs (me-too status)	Seretide Diskus 100mcg + 50Mcg GSK Pakistan. (Reg.no.074726)
	GMP status of the Finished product manufacturer	New section approval letter granted on 20/09/2021 (Dry Powder Inhaler and Nasal Drops) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd. Address: A-14/15, MIDC Area, Chincholi, Solapur, 413255Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of both drug substances are present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Fluticasone Propionate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(FTP0010414,FTP-0020715,FTP-0010615) Salmeterol Xinafoate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (SX-0020515,SX-0030515,SX-0040515)
	Module-III (Drug Product):	The firm has submitted description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence report has not submitted by the firm.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Flutimet Turbo haler is an inspiratory flow driven,multidose powder inhaler.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vamsi Labs Ltd. Address: A-14 & 15, MIDC Area, Chincholi, Solapur, Maharashtra 413255, India		
API Lot No.	Firm has not mentioned the API lot no. of both drug substances.		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	T-46	T-47	T-48
Batch Size	500 Capsule	500 Capsule	500 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	25-12-2021	25-12-2021	25-12-2021

No. of Batches	03	
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.
2.	3.2.S.4.1-3.2.S.4.2	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
3.	3.2.S.4.3	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.
4.	3.2.S.4.4 (Fluticasone)	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph. Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer,since it was evident from the batch analysis report that you have perfoemd Particle size test by Malvern.
5.	3.2.S.7.3 (Salmetrol Xinafoate)	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.
6.	3.2.P.1	• Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules. • Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of

		salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins). • Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
7.	3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.
8.	3.2.P.2.3	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
9.	3.2.P.5.2	• Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph. • Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test, clarification is required in this regard.
10	3.2.P.5.3	Provide analytical method verification report of drug product in compliance of USP monograph.
11	3.2.P.5.4	• Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. • Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformity.
12	3.2.P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.
13	3.2.P.8	• Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. • Provide Reference of previous approval of applications with stability study data of the firm (if any) • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
14	2.3 R.1.1	• Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. • Calculation of dispensed weight of active along with salt and factor adjustment was not given in the BMR,please provide the calculations.

15	Amendment in QOS (Module 2) for above points.	
Decision: Deferred for submission of reply of above-cited shortcomings within six month.		
1911.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32465 dated 11/11/2022
	Details of fee submitted	PKR 30,000/-:dated 19/10/2022
	The proposed proprietary name / brand name	Flutimet 250/50mcg Rota Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluticasone Propionate……250mcg Salmeterol Xinafoate ……50mcg
	Pharmaceutical form of applied drug	White to off white color powder filled in hard gelatin capsule shells
	Pharmacotherapeutic Group of (API)	Long Acting- Beta agonists Corticosteroids
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved ADVAIR DISKUS 100/50
	For generic drugs (me-too status)	Seretide Diskus 250mcg + 50mcg GSK Pakistan. (Reg.no.074727)
	GMP status of the Finished product manufacturer	New section approval letter granted on 20/09/2021 (Dry Powder Inhaler and Nasal Drops) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd. Address: A-14/15, MIDC Area, Chincholi, Solapur, 413255Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	Official monograph of both drug substances are present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Fluticasone Propionate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(FTP0010414,FTP-0020715,FTP-0010615) Salmeterol Xinafoate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (SX-0020515,SX-0030515,SX-0040515)
	Module-III (Drug Product):	The firm has submitted description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence report has submitted against the brand leader seretide Rotacaps 250/50mcg of M/s. Glaxo Smith Kline B.no. R102 Exp date 11-2023 (Identification,assay)
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Flutimet Turbo haler is an inspiratory flow driven,multidose powder inhaler.
STABILITY STUDY DATA		
Manufacturer of API	M/s Vamsi Labs Ltd. Address: A-14 & 15, MIDC Area, Chincholi, Solapur, Maharashtra 413255, India	
API Lot No.	Firm has not mentioned the API lot no. of both drug substances.	
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)	
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	

Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.		T-49	T-50	T-51
Batch Size		500 Capsule	500 Capsule	500 Capsule
Manufacturing Date		12-2021	12-2021	12-2021
Date of Initiation		25-12-2021	25-12-2021	25-12-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted		

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.
2.	3.2.S.4.1- 3.2.S.4.2	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
3.	3.2.S.4.3	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.
4.	3.2.S.4.4 (Fluticasone)	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph. Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer,since it was evident from the batch analysis report that you have performed Particle size test by Malvern.

5.	3.2.S.7.3 (Salmetrol Xinafoate)	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.
6.	3.2.P.1	• Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules. • Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins). • Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
7.	3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.
8.	3.2.P.2.3	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
9.	3.2.P.5.2	• Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph. • Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test,clarification is required in this regard.
10	3.2.P.5.3	Provide analytical method verification report of drug product in compliance of USP monograph.
11	3.2.P.5.4	• Justify for not performing the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. • Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformit.
12	3.2.P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.
13	3.2.P.8	• Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and test for specified microorganism and foreign particulate matter while performing the stability study of drug product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.

		• Provide Reference of previous approval of applications with stability study data of the firm (if any) • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
14	2.3 R.1.1	• Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. • Calculation of dispensed weight of active alomg with salt and factor adjustment was not given in the BMR,please provide the calculations.
15	Amendment in QOS (Module 2) for above points.	

Decision: Deferred for submission of reply of above-cited shortcomings within six month.

1912.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32465 dated 11/11/2022
	Details of fee submitted	PKR 30,000/-:dated 19/10/2022
	The proposed proprietary name / brand name	Flutimet 250/50mcg Rota Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Fluticasone Propionate……250mcg Salmeterol Xinafoate ……50mcg
	Pharmaceutical form of applied drug	White to off white color powder filled in hard gelatin capsule shells
	Pharmacotherapeutic Group of (API)	Long Acting- Beta agonists Corticosteroids
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved ADVAIR DISKUS 100/50
	For generic drugs (me-too status)	Seretide Diskus 250mcg + 50mcg GSK Pakistan. (Reg.no.074727)
	GMP status of the Finished product manufacturer	New section approval letter granted on 20/09/2021 (Dry Powder Inhaler and Nasal Drops) section approved.
	Name and address of API manufacturer.	M/s Vamsi Labs Ltd.

		Address: A-14/15, MIDC Area, Chincholi, Solapur, 413255Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of both drug substances are present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Fluticasone Propionate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(FTP0010414,FTP-0020715,FTP-0010615) Salmeterol Xinafoate Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (SX-0020515,SX-0030515,SX-0040515)
	Module-III (Drug Product):	The firm has submitted description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence report has submitted against the brand leader seretide Rotacaps 500/50mcg of M/s. Glaxo Smith Kline B.no. R104 Exp date 11-2023. (identification, assay)
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

	Description of the delivery devices (Inhaler intended to be marketed along applied formulation)	Flutimet Turbo haler is an inspiratory flow driven,multidose powder inhaler.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Vamsi Labs Ltd. Address: A-14 & 15, MIDC Area, Chincholi, Solapur, Maharashtra 413255, India		
API Lot No.		Firm has not mentioned the API lot no. of both drug substances.		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.		T-52	T-53	T-54
Batch Size		500 Capsule	500 Capsule	500 Capsule
Manufacturing Date		12-2021	12-2021	12-2021
Date of Initiation		25-12-2021	25-12-2021	25-12-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted		

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	Justify the finished product specifications as "Manufacturer's specifications" since the drug product monograph is available in USP. Revise your specifications along with submission of requisite fee.
2.	3.2.S.4.1-3.2.S.4.2	Submit data for both drug substance in section 3.2.S.4.1 and 3.2.S.4.2 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required", since you

		have only submitted analytical procedure by drug substance manufacturer which is also not in accordance with USP.
3.	3.2.S.4.3	Submit data for both drug substances in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.
4.	3.2.S.4.4 (Fluticasone)	Drug substance specifications shall include test of specific optical rotation as recommended by BP monograph. Evidence of availability of MALVERN mastersizer instrument by drug product manufacturer,since it was evident from the batch analysis report that you have perfoemd Particle size test by Malvern.
5.	3.2.S.7.3 (Salmetrol Xinafoate)	Accelerated stability data of third batch was of Formetrol Fumarate Hydrate instead of Salmetrol Xinafoate, please submit the correct data.
6.	3.2.P.1	• Submitted details of accompanying device is for the multidose pre-filled dry powder inhaler instead of inhaler device required for DPI capsules. • Composition of drug product given in section 3.2.P.1 (d) is different from the composition of innovator brand approved in USFDA, according to the label of innovator brand Each blister on the strip contains a white powder mix of micronized fluticasone propionate (100, 250, or 500 mcg) and micronized salmeterol xinafoate salt (72.5 mcg, equivalent to 50 mcg of salmeterol base) in 12.5 mg of formulation containing lactose monohydrate (which contains milk proteins). • Provide the details regarding the metered amount and the mass of the drug delivered from the mouthpiece under defined test conditions (i.e., flow rate, duration).
7.	3.2.P.2.2.1	Pharmaceutical equivalence report against the innovator/reference product shall be submitted including results for batch release tests in accordance with USP for both applied and reference formulation. Submit Pharmaceutical equivalence report of strength 100/50mcg by performing all the quality test mentioned in USP.
8.	3.2.P.2.3	Manufacturing procedure submitted in section 3.2.P.2.3 and 3.2.P.3 reflect that particle size of powder is further reduced till 3µm, please provide details and evidence of availability of sheer mixer and the instrument/particle size analyzer used for the analysis of final particle size achieved.
9.	3.2.P.5.2	• Submit detailed analytical procedure used for testing of drug product in accordance with USP monograph. • Batch release specification did not include the performance test for inhalation powder i.e. Delivered Dose Uniformity & Aerodynamic Size Distribution test,clarification is required in ths regard.
10	3.2.P.5.3	Provide analytical method verification report of drug product in compliance of USP monograph.
11	3.2.P.5.4	• Justify for not perfoming the test of microbial enumeration test and test for specified microorganism and foreign particulate matter test while batch release of drug product. • Further provide evidence of availability of Cascade impaction sampling apparatus for performance of Aerodynamic Size Distribution test and sampling apparatus used for the performance of Delivered Dose Uniformit.
12	3.2.P.6	Provide certificate of analysis of reference standard /working standard used for testing of the product.
13	3.2.P.8	• Justify for not performing the test Delivered Dose Uniformity, Aerodynamic Size Distribution test, test of microbial enumeration test and

		test for specified microorganism and foreign particulate matter while performing the stability study of drug product. • Submit compliance record of HPLC software 21CFR & audit trail reports on product testing for each analysis performed during the study. • Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. • Provide Reference of previous approval of applications with stability study data of the firm (if any) • Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
14	2.3 R.1.1	• Manufacturing procedure mentioned in BMR is different from the manufacturing procedure given in 3.2.P.3, justification is required in this regard. • Calculation of dispensed weight of active alomg with salt and factor adjustment was not given in the BMR,please provide the calculations.
15	Amendment in QOS (Module 2) for above points.	

Decision: Deferred for submission of reply of above-cited shortcomings within six month.

Previously Deferred Cases of New section:

1913.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9107 dated 11-04-2022
	Details of fee submitted	Rs.30,000/- dated 28-03-2022
	The proposed proprietary name / brand name	**Cef-Sulb Injection 1gm**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder Cefoperazone sodium MS equivalent to Cefoperazone……..500mg Sterile Powder Sulbactam sodium MS equivalent to Sulbactam…….500mg
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection

	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 1gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 1gm by Global Pharmaceuticals, Reg. No. 042552
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefoperazone sodium /Sulbactam sodium eq to Cefoperazone /Sulbactam not present in any pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (T-CSP001, T-CSP002, T-CSP003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Toxirid Injection 1gm by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).

	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China		
API Lot No.	CEFP17/023/06/21		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-CSP001	T-CSP001	T-CSP001
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	26-09-2021	26-09-2021	26-09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20191025 issued by CFDA valid till 10/12/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Letter No. 11160/2021/DRAP Dated: 27-07-2021 B/L No. 176-6445-291 dated: 31-07-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Deficiencies/ Short-comings
Shortcomings communicated to the Firm: • You have mentioned USP specification in section 1.5.6 in module 1, while the drug product monograph is not available in USP, but present in JP. Revise the specifications along with submission of requisite fee. • The drug substance manufacturer has claimed both USP and in-house standards for the drug substance, provide scientific justification in this regard. • Justify, how you have claimed USP specification for drug substance cefoperazone sodium+Sulbactum30-May-22 sodium, when the monograph has not been present in USP.

- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance manufacturers."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Stability study data of 3 batches of drug substances till the assigned shelf life needs to be submitted, since stability data of 3 months has submitted despite the batch had been manufactured in 2017.
- Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".
- Justify the use of 4ml printed glass vial for packaging of drug product with reference to the volume of diluent used for reconstitution of dry powder for injection as per innovator product.
- Justify how you have performed pharmaceutical equivalence studies using the reference product of different strength.
- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting of Registration Board, which states that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".
- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"
- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Justify the weight variation limit of filled vial from1107-1152mg with reference to the claimed potency of both actives.
- Provide the Pharmacopeial reference of finished product specifications, since USP specs are mentioned in module 1, and USP does not contain any monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection. However, monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopeia.
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the document submitted in section 3.2.P.8 batch no. T-CSP-002 and T-CSP-003 has been manufactured on 02-2021, while stability study data sheet submitted in section 3.2.P.8.3 stated these batches were manufactured in sep-2021. Clarification required in this regard.
- Specify the batch size of all three stability batches.
- Justify the pH acceptance criteria (6.0-8.0) and water content acceptance limit (8.0-11%) set for drug product with the acceptance criteria mentioned on COA of drug substance by drug substance manufacturer i.e. 4.5-6.5 and NMT 3.0%. Elevation of pH and water content of drug product without any further processing of formulation needs to be justify with the pharmacopeial reference and innovator product.
- Assay content of both active should be separately calculated and mentioned as per pharmacopeial reference and innovator product.

- As per release specification of drug product acceptance criteria of assay is 90-110% while the stability data sheet represents that assay content should be between 90-115%. Justification is required regarding the variation in acceptance limit of assay content in various section of module-III.
- Justify why the sterility test is not included in the stability studies of the product.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
- In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.

Remarks of the Evaluator:

In response of above shortcomings, firm has submitted a complete new CTD dossier with fee of Rs.7500/- in which drug substance was imported from a new source and accordingly data of trial batches of drug product manufactured from new source of drug substance has submitted. Newly submitted dossier has again evaluated and presented below before the Board for its consideration.

1914.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22143 dated 11/04/2022
	Details of fee submitted	PKR 7,500/-: dated 02/08/2022
	The proposed proprietary name / brand name	**Cef-Sulb Injection IV/IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder Cefoperazone sodium JP equivalent to Cefoperazone…….500mg Sterile Powder Sulbactam sodium JP equivalent to Sulbactam…….500mg
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Sulperazone Injection 1gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 1gm by Global Pharmaceuticals, Reg. No. 042552
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co. Ltd. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefoperazone sodium /sulbactam sodium Injection is present in JP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (2003FJ81NH, 2002FJ81NH, 2001FJ81NH)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product 2SUM (Cefoperazone Sodium + Sulbactam Sodium) 1g Injection of M/s. Healthtek Pvt. Ltd. Karachi, performing quality tests (Identification, Assay, constituted solution, BET & sterility test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	Qilu Antibiotic Pharmaceutical Co. Ltd. China	

API Lot No.	2001FJ81NH		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRI003-01	TRI003-01	TRI003-01
Batch Size	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	26-01-2022	26-01-2022	26-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Qilu Antibiotics Pharmaceuticals Co. Ltd., China vide Dy. No. 11160/2021 DRAP Dated: 27-12-2021. Invoice attested vide Dy.no. 11160/2021 DRAP dated: 27-12-2021in which shipper was M/s. Shandong Luoxin Pharmaceuticals, China.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Shortcomings/Observations
1.	3.2. S.4.1	Acceptance criteria of assay mentioned in specification of drug was not in accordance with JP monograph. Assay limit mentioned in COA and specification of drug substance by both drug substance manufacturer and drug product manufacturer was Cefoperazone on anhydrous basis ≥43.5% and sulbactam on anhydrous basis ≥44.5%. / Assay acceptance criteria in accordance with JP monograph is "It contains not less than 90.0% and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24)".
2.	3.2. S.4.3	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.

<table>
<tr><td>3.</td><td>3.2. S.5</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug substance.</td></tr>
<tr><td>4.</td><td>3.2. S.7</td><td>Firm has submitted only 6 months long term stability data of all three batches of drug substance.</td></tr>
<tr><td>5.</td><td>3.2P.2.1(a)(b)</td><td>Firm has not provided any details related to weight of powder filled per vial keeping in view the sodium content of both active substances.</td></tr>
<tr><td>6.</td><td>3.2.P.2.1(C)</td><td>Firm has not provided any details regarding the type of diluent, its composition, quantity or volume, specifications (as applicable) in which drug product has to be reconstitute before administration.</td></tr>
<tr><td>7.</td><td>3.2. P.2.2.1</td><td>Firm has submitted the pharmaceutical equivalence report in which the acceptance criteria of all the quality test was not in accordance with JP monograph:
<table>
<tr><td>Acceptance criteria in pharmaceutical equivalence report</td><td>Acceptance criteria in JP monograph</td></tr>
<tr><td>pH (6.0-8.8)</td><td>pH (4.5-6.5)</td></tr>
<tr><td>Assay (90%-110%)</td><td>Assay (It contains not less than 90.0 and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24).)</td></tr>
<tr><td>Bacterial Endotoxin Test (NMT 0.2 USP Endotoxin unit per mg)</td><td>Bacterial Endotoxin Test (Less than 0.060 EU/mg (potency).)</td></tr>
</table>
Further firm has not performed water content test and clarity and color of solution test which are also included in JP monograph.</td></tr>
<tr><td>8.</td><td>3.2. P.5.2</td><td>Firm has not submitted the analytical procedure used for testing of drug product.</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>Analytical method verification report reflects that the assay has performed on UV method while the JP monograph recommends the HPLC method for assay of drug product.</td></tr>
<tr><td>10.</td><td>3.2.P.6</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.</td></tr>
<tr><td>11.</td><td>3.2.P.8</td><td>Firm has not submitted following documents to support the stability data of drug product:
Reference of previous approval of applications with stability study data of the firm (if any)
Documents for the procurement of API with approval from DRAP (in case of import).
Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.</td></tr>
<tr><td>12.</td><td>3.2.R</td><td>Firm has not submitted the copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.</td></tr>
</table>

Decision of 321st meeting of Registration Board:

- Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.
- Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
- Submit long term stability data of drug substance till the claimed shelf life.
- Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.
- Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.
- Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.
- Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug product.
- Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.
- Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Reply of the Firm:

Sr.no.	Decision	Response of the Firm
1.	Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.	Firm replied that "Ask the supplier about analytical method verification ,will be dispatched soon".
2.	Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.	Firm replied that "By mistake it was attached, actual criteria of drug substance as per JP monograph".
3.	COA of primary / secondary reference standard including source and lot number used for testing of drug substance.	Firm submitted the COA of USP primary reference standard
4.	Submit long term stability data of drug substance till the claimed shelf life.	Firm replied that " Ask to supplier for long term stability, will be dispatched soon."
5.	Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.	Firm submitted the formulation table in which only the material has been listed with the information that the API (cefoperazone sodium plus sulbactum sodium) was used 3% in excess, while the calculation of dispense quantity of API per vial was not submitted by the firm.
6.	Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.	Firm submitted the pharmaceutical equivalence report in which all the quality test has been performed.
7.	Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.	Submitted

	8. Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.	Submitted
	9. COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted
	10. Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.
	11. Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Not submitted
	12. Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Not submitted
	13. Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm submitted the fee of Rs.30,000/- vide slip no. 057382167110 dated 04-11-2022

Decision: Deferred for submission of following:

- **Submit analytical method verification studies including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.**
- **COA of primary / secondary reference standard including source and lot number used for testing of drug substance.**
- **Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.**
- **Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.**
- **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.**

1915.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 9108 dated 11-04-2022
	Details of fee submitted	PKR 30,000/-: dated 28/03/2022
	The proposed proprietary name / brand name	**Cef-Slub Injection IV/IM**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefoperazone sodium MS equivalent to Cefoperazone 1g Sterile Powder of Sulbactam sodium MS equivalent to Sulbactam 1g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 2gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 2gm by Global Pharmaceuticals, Reg. No. 042555
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefoperazone sodium /Sulbactam sodium eq to Cefoperazone /Sulbactam is present not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (T-CSP001, T-CSP002, T-CSP003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure

		(including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Toxirid Injection 2gm by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Shandong Luoxin Pharmaceutical Co.,Ltd China		
API Lot No.	CEFP17/023/06/21		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-CSP001	T-CSP001	T-CSP001
Batch Size	1000 Vials	1000 Vials	1000 Vials
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	26-09-2021	26-09-2021	26-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20191025 issued by CFDA valid till 10/12/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Letter No. 11160/2021/DRAP Dated: 27-07-2021 B/L No. 176-6445-291 dated: 31-07-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Deficiencies/ Short-comings
Shortcomings communicated to the Firm:

- You have mentioned USP specification in section 1.5.6 in module 1, while the drug product monograph is not available in USP, but present in JP. Revise the specifications along with submission of requisite fee.
- The drug substance manufacturer has claimed both USP and in-house standards for the drug substance, provide scientific justification in this regard.
- Justify, how you have claimed USP specification for drug substance cefoperazone sodium+Sulbactum30-May-22 sodium, when the monograph has not been present in USP.
- Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance manufacturers."
- Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Stability study data of 3 batches of drug substances till the assigned shelf life needs to be submitted, since stability data of 3 months has submitted despite the batch had been manufactured in 2017.
- Submit data in section 3.2.P.1 (c) as per the decision of 293rd meeting of Registration Board, which states that "Provide information including type of diluent, its composition, quantity or volume, specifications (as applicable) and regulatory status in Pakistan (as applicable) for the diluent which is to be provided along with the applied drug".
- Justify the use of 4ml printed glass vial for packaging of drug product with reference to the volume of diluent used for reconstitution of dry powder for injection as per innovator product.
- Justify how you have performed pharmaceutical equivalence studies using the reference product of different strength.
- Submit data in section 3.2.P.2.3 (Manufacturing process development) as per the decision of 293rd meeting of Registration Board, which states that "The selection and optimization of the manufacturing process described in 3.2.P.3.3, in particular its critical aspects, shall be explained. Any specific manufacturing process development shall be provided e.g., sterilization shall be explained and justified. Where relevant, justification for the selection of aseptic processing or other sterilization methods over terminal sterilization shall be provided".
- Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"
- Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.
- Justify the weight variation limit of filled vial from1107-1152mg with reference to the claimed potency of both actives.
- Provide the Pharmacopeial reference of finished product specifications, since USP specs are mentioned in module 1, and USP does not contain any monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection. However, monograph for Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopeia.
- Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.
- According to the document submitted in section 3.2.P.8 batch no. T-CSP-002 and T-CSP-003 has been manufactured on 02-2021, while stability study data sheet submitted in section 3.2.P.8.3 stated these batches were manufactured in sep-2021. Clarification required in this regard.
- Specify the batch size of all three stability batches.
- Justify the pH acceptance criteria (6.0-8.0) and water content acceptance limit (8.0-11%) set for drug product with the acceptance criteria mentioned on COA of drug substance by drug substance manufacturer

i.e. 4.5-6.5 and NMT 3.0%. Elevation of pH and water content of drug product without any further processing of formulation needs to be justify with the pharmacopeial reference and innovator product.

- Assay content of both active should be separately calculated and mentioned as per pharmacopeial reference and innovator product.
- As per release specification of drug product acceptance criteria of assay is 90-110% while the stability data sheet represents that assay content should be between 90-115%. Justification is required regarding the variation in acceptance limit of assay content in various section of module-III.
- Justify why the sterility test is not included in the stability studies of the product.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Provide Reference of previous approval of applications with stability study data of the firm (if any)
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).
- In-use stability studies of reconstituted suspension is required along with proposed in-use storage statement and in-use shelf-life.

Remarks of the Evaluator:

In response of above shortcomings, firm has submitted a complete new CTD dossier with fee of Rs.7500/- in which drug substance was imported from a new source and accordingly data of trial batches of drug product manufactured from new source of drug substance has submitted. Newly submitted dossier has again evaluated and presented below before the Board for its consideration.

1916.	Name, / Marketing Authorization Holder address of Applicant	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22144 dated 04/08/2022
	Details of fee submitted	PKR 7,500/-: dated 02/08/2022
	The proposed proprietary name / brand name	**Cef-Slub Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefoperazone sodium JP equivalent to Cefoperazone 1g Sterile Powder of Sulbactam sodium JP equivalent to Sulbactam 1g
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	JP Specifications
	Proposed Pack size	1×1's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone Injection 2gm by M/s Pfizer Ltd. USA, USFDA Approved.
	For generic drugs (me-too status)	Toxirid Injection 2gm by Global Pharmaceuticals, Reg. No. 042555
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co. Ltd. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of cefoperazone sodium /sulbactam sodium Injection is present in JP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 6 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (2003FJ81NH, 2002FJ81NH, 2001FJ81NH)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product 2SUM (Cefoperazone Sodium + Sulbactam Sodium) 2g Injection of M/s. Healthtek Pvt. Ltd. Karachi, performing quality tests (Identification, Assay, constituted solution, BET & sterility test).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Qilu Antibiotic Pharmaceutical Co. Ltd. China		
API Lot No.	2001FJ81NH		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TRI004-01	TRI004-01	TRI004-01
Batch Size	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	26-01-2022	26-01-2022	26-01-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Qilu Antibiotics Pharmaceuticals Co. Ltd., China vide Dy. No. 11160/2021 DRAP Dated: 27-12-2021. Invoice attested vide Dy.no. 11160/2021 DRAP dated: 27-12-2021in which shipper was M/s. Shandong Luoxin Pharmaceuticals, China.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Section	Shortcomings/Observations

<table>
<tr><td>1.</td><td>3.2. S.4.1</td><td>Acceptance criteria of assay mentioned in specification of drug was not in accordance with JP monograph.<table><tr><td>Assay limit mentioned in COA and specification of drug substance by both drug substance manufacturer and drug product manufacturer was Cefoperazone on anhydrous basis ≥43.5% and sulbactam on anhydrous basis ≥44.5%.</td><td>Assay acceptance criteria in accordance with JP monograph is “It contains not less than 90.0% and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24)”.</td></tr></table></td></tr>
<tr><td>2.</td><td>3.2. S.4.3</td><td>Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.</td></tr>
<tr><td>3.</td><td>3.2. S.5</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug substance.</td></tr>
<tr><td>4.</td><td>3.2. S.7</td><td>Firm has submitted only 6 months long term stability data of all three batches of drug substance.</td></tr>
<tr><td>5.</td><td>3.2P.2.1(a)(b)</td><td>Firm has not provided any details related to weight of powder filled per vial keeping in view the sodium content of both active substances.</td></tr>
<tr><td>6.</td><td>3.2.P.2.1(C)</td><td>Firm has not provided any details regarding the type of diluent, its composition, quantity or volume, specifications (as applicable) in which drug product has to be reconstitute before administration.</td></tr>
<tr><td>7.</td><td>3.2. P.2.2.1</td><td>Firm has submitted the pharmaceutical equivalence report in which the acceptance criteria of all the quality test was not in accordance with JP monograph:<table><tr><td>Acceptance criteria in pharmaceutical equivalence report</td><td>Acceptance criteria in JP monograph</td></tr><tr><td>pH (6.0-8.8)</td><td>pH (4.5-6.5)</td></tr><tr><td>Assay (90%-110%)</td><td>Assay (It contains not less than 90.0 and not more than 110.0% of the labeled potency of cefoperazone (C25H27N9O8S2: 645.67), and not less than 95.0% and not more than 110.0% of the labeled potency of sulbactam (C8H11NO5S: 233.24).)</td></tr><tr><td>Bacterial Endotoxin Test (NMT 0.2 USP Endotoxin unit per mg)</td><td>Bacterial Endotoxin Test (Less than 0.060 EU/mg (potency).)</td></tr></table>Further firm has not performed water content test and clarity and color of solution test which are also included in JP monograph.</td></tr>
<tr><td>8.</td><td>3.2. P.5.2</td><td>Firm has not submitted the analytical procedure used for testing of drug product.</td></tr>
<tr><td>9.</td><td>3.2.P.5.3</td><td>Analytical method verification report reflects that the assay has performed on UV method while the JP monograph recommends the HPLC method for assay of drug product.</td></tr>
<tr><td>10.</td><td>3.2.P.6</td><td>Firm has not submitted the COA of primary / secondary reference standard including source and lot number used for testing of drug product.</td></tr>
<tr><td>11.</td><td>3.2.P.8</td><td>Firm has not submitted following documents to support the stability data of drug product:
Reference of previous approval of applications with stability study data of the firm (if any)
Documents for the procurement of API with approval from DRAP (in case of import).
Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.</td></tr>
</table>

		• Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin. • Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.
12.	3.2.R	Firm has not submitted the copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Decision of 321st meeting of Registration Board:

- Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.
- Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
- Submit long term stability data of drug substance till the claimed shelf life.
- Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.
- Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.
- Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.
- Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.
- COA of primary / secondary reference standard including source and lot number used for testing of drug product.
- Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.
- Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Reply of the Firm:

Sr.no.	Decision	Response of the Firm
1.	Submit analytical method verification studies including results of specificity and accuracy parameters as per requirement of section 3.2.S.4.3 of Form-5F.	Firm replied that "Ask the supplier about analytical method verification ,will be dispatched soon".
2.	Justification for adopting the acceptance criteria of assay of drug substance different from that specified in JP monograph.	Firm replied that "By mistake it was attached, actual criteria of drug substance as per JP monograph".
3.	COA of primary / secondary reference standard including source and lot number used for testing of drug substance.	Firm submitted the COA of USP primary reference standard
4.	Submit long term stability data of drug substance till the claimed shelf life.	Firm replied that " Ask to supplier for long term stability, will be dispatched soon."

5.	Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.	Firm submitted the formulation table in which only the material has been listed with the information that the API (cefoperazone sodium plus sulbactum sodium) was used 3% in excess, while the calculation of dispense quantity of API per vial was not submitted by the firm.
6.	Submit pharmaceutical equivalence report, in which all the quality test should performed in compliance with JP monograph.	Firm submitted the pharmaceutical equivalence report in which all the quality test has been performed.
7.	Submit analytical procedure used for testing of drug product under section 3.2.P.5.2.	Submitted
8.	Submit analytical method verification report of assay testing performed on HPLC in compliance with JP monograph.	Submitted
9.	COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted
10.	Details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the invoice of import of drug substance according to which, supplier of the drug substance was M/s. Shandong Luoxin Pharmaceutical Co., Ltd China and quantity of 5kg has been imported and clearance granted on 27-12-2021 vide dy.no.11160/2021 DRAP. While the firm has also submitted Form-6 along with the invoice in which license to import drug from Qilu Antibiotics Pharmaceuticals Co. Ltd. China has given on 27-12-2021 vide Dy.no. 11160/2021 DRAP.
11.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Not submitted
12.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Not submitted
13.	Full fee of Rs. 30,000 for revision of stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm submitted the fee of Rs.30,000/- vide slip no. 057382167110 dated 04-11-2022

Decision: Deferred for submission of following:

- **Submit analytical method verification studies including results of specificity and accuracy parameters by drug product manufacturer as per requirement of section 3.2.S.4.3 of Form-5F.**
- **COA of primary / secondary reference standard including source and lot number used for testing of drug substance.**
- **Submit weight of powder filled per vial keeping in view the sodium content of both active substances, under section 3.2.P.2.1.**
- **Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.**
- **Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.**

1917.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.11609 dated 13/05/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Citi-Pime Injection 1gm
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL with L- Arginine Eq. to Cefepime 1g
	Pharmaceutical form of applied drug	Intra-venous / Intra-muscular Injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 1g by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Zepime Injection 1g by Global Pharmaceuticals, Reg. No. 046016
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefepime HCL with L-Arginine is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator brand that is Zepime Injection 1g by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Ltd India		
API Lot No.	CFM-2104004		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocaine along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TC006-001	TC006-002	TC006-003
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	02-2023	02-2023	02-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Kopran Research laboratories,India vide Dy. No. 6176 Dated: 16-04-2021. Invoice attested vide Dy.no. 6017/2021 DRAP dated: 22-04-2021in which exporter was M/s. Kopran Research laboratories, India
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

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

Remarks OF Evaluator:

Sr.no.	Section	Observations/Shortcomings	Reply of the Firm
1.	3.2.S.4.1 3.2. S.4.2	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm has not submitted the specifications and analytical procedure of drug substance by drug product manufacturer.
2.	3.2. S.4.3	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2. S.7	Submit complete long-term stability data of all three batches of drug substance, since only the complete data of batch no. CEIV/B1203011 has been submitted in section 3.2. S.7.	Firm has not submitted the long-term stability data of batch no. CEIV/B1203013.
4.	3.2. P.2.6	Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"	Firm has not submitted the reply in response of this query.
5.	3.2. P.3.1	Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail manufacturing procedure given in section 3.2. P.3.3.	Firm has submitted the amended document in which cefepime HCl with L-arginine is mentioned as the only active ingredient. However, the information regarding the quantity of dry powder filled per vial has not been given. Further, the flow chart of manufacturing process submitted in the reply of section 3.2.P.3.3 is of ceftriaxone.
6.	3.2.P.5.2	Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm again submit the copy of monograph of USP in section 3.2.P.5.2 and in section 3.2.P.4.2 submit the analytical procedure of cefotaxime injection.

7.	3.2.P.5.3	Analytical method of drug product verified in section 3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.	Firm has not given the reply in response of this query.
8.	3.2.P.5.4	Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product	firm has submitted batch analysis report of three trail batches TRA-001, TRA-002, TRA-003 which were not the batch numbers of trial batches used for stability studies as evident from the submitted stability data sheets. Further, the test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test was not been included in batch analysis report nor given any justification. Furthermore, the firm submitted the same batch analysis report for cefepime 500mg injection and cefepime 1gm injection.
9.	3.2.P.6	Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.	Firm has submitted the reply in response of this query.
10.	3.2.P.8	Submit the stability data sheet of cefepime injection, since the submitted sheets are of ceftriaxone.	Firm stated that rectified and corrected stability data sheets are submitted.
11.	3.2.P.8	According to the document submitted in section 3.2. P.8 batch no. Cef-P-004, Cef-P-005and Cef-P-006 has been manufactured on 09-2021, while the dossier submitted in R&I of DRAP on 13th May,2022i.e. after 8 months of manufacturing of trial batches, clarification is required how you have submitted the stability data of real time study till 24month.	Firm stated that rectified and corrected stability data sheets are submitted. However, the firm submitted the raw data sheets of batch no. TC006-01, TC006-02, TC006-03.
12.		1. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. 2. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. 3. Provide Reference of previous approval of applications with stability study data of the firm (if any) 4. Documents for the procurement of API with approval from DRAP (in case of import).	Firm has only submitted the chromatograms and 21 CFR audit trail report of instant product. Remaining documents has not been provided by the firm.

		5. Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. 6. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). 7. In-use stability studies of reconstituted injection is required along with proposed in-use storage statement and in-use shelf-life. 8. Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	

Decision of 321st meeting of Registration Board:

- Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.
- Analytical method verification report of drug substance performed by drug product manufacturer.
- Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.
- Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.
- Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.
- Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.
- Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.
- Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.
- Batch analysis report of all three trial batches, in which all the quality test should be included that are specify in USP monograph of Cefepime injection.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Reply of the Firm:

Sr.no.	Decision of Registration Board	Response of Firm
1.	Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm submitted the specification and analytical procedure of drug substance by drug substance manufacturer instead from drug product manufacturer.
2.	Analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the USP monograph.
3.	Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.	submitted

4.	Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.	submitted
5.	Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.	Not submitted
6.	Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.	Submitted
7.	Analytical method verification report of assay testing of drug product ,in compliance of USP monograph of Cefepime Injection	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the USP monograph.
8.	Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.	Firm submitted the batch analysis report of three trial batches (TC006-001,TC006-002,TC006-003), Further the stability data sheet of real time stability study and COA of individual time points were of trial batches TC007-001,TC007-02,TC007-03.
9.	• Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the form-6 bearing the dy.no. 6176 dated 16-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine. Firm submitted the commercial invoice bearing the dy.no. 6017/2021 DRAP dated 22-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine.
10.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	As per the submitted raw data sheets and chromatograms it is evident that firm has not applied the chromatographic condition with reference to mobile phase program, injection volume and sample conc. as recommended by USP.
11.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3	Not submitted

Decision: Deferred for submission of following:

- **Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.**
- **Manufacturer will provide analytical method verification studies for drug substance by drug product manufacturer as per USP including specificity, accuracy and precision before the issuance of registration letter.**
- **Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.**
- **Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.**
- **Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.**
- **Clarification required for not applied the same chromatographic condition for assay testing of drug product as recommended by USP monograph of cefepime injection, as evident from the submitted raw data sheets and chromatograms of stability batches.**
- **Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3**

1918.	Name, address of Applicant / Marketing Authorization Holder	M/s Citi Pharma Private Limited
	Name, address of Manufacturing site.	M/s Citi Pharma Private Limited Factory: 3 K.M, Head Balloki Road, Phool Nagar, Distt. Kasur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11608 dated 13/05/2022
	Details of fee submitted	PKR 30,000/-: dated 01/11/2021
	The proposed proprietary name / brand name	Citi-Pime Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Sterile Powder of Cefepime HCL with L-Arginine Eq. to Cefepime 500mg
	Pharmaceutical form of applied drug	Dry powder for injection
	Pharmacotherapeutic Group of (API)	Broad-spectrum cephalosporin antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime Injection 500mg by M/s Hospira Inc. USA, USFDA Approved.
	For generic drugs (me-too status)	Zepime Injection 500mg by Global Pharmaceuticals, Reg. No. 046015
	GMP status of the Finished product manufacturer	New license granted on 21/09/2021 Cephalosporin section approved.
	Name and address of API manufacturer.	M/s Kopran Research Laboratories Ltd,Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cefepime for injection is present in USP. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (CEIV/B1203011, CEIV/B1203012, CEIV/B1203013)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zepime Injection 500mg by Global Pharmaceuticals Pakistan performing quality tests (Identification, Assay, Constituted Solution, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Kopran Research Laboratories Ltd India		
API Lot No.	CFM-2104004		
Description of Pack (Container closure system)	One clear glass vial 15ml with LDPE ampoule of WFI or 1% Lidocaine along with leaflet in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TC006-001	TC006-002	TC006-003
Batch Size (Scientifically rational batch size)	Not mentioned	Not mentioned	Not mentioned
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	02-2023	02-2023	02-2023
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has not submitted the requisite document.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Form-6 grant permission for license to import from M/s. Kopran Research laboratories, India vide Dy. No. 6176 Dated: 16-04-2021.

		Invoice attested vide Dy.no. 6017/2021 DRAP dated: 22-04-2021in which exporter was M/s. Kopran Research laboratories, India
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Raw data sheets and chromatograms attached.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Observations/Shortcomings	Reply of the Firm
1.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm has not submitted the specifications and analytical procedure of drug substance by drug product manufacturer.
2.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted"	Firm has not submitted the analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit complete long-term stability data of all three batches of drug substance, since only the complete data of batch no. CEIV/B1203011 has been submitted in section 3.2. S.7.	Firm has not submitted the long-term stability data of batch no. CEIV/B1203013.
4.	Submit the data of compatibility studies in section 3.2.P.2.6 as per the decision of 293rd meeting of Registration Board, which states that "*Compatibility studies for the dry powder for injections and dry powder for suspension should be performed as per the instructions provided in individual label of the drug product*"	Firm has not submitted the reply in response of this query.
5.	Batch formula mentioned in section 3.2.P.3.1 evident that only the active ingredient is the part of batch formula, while manufacturing procedure specified in section 3.2.P.3.3 stated that "solution has been prepared in 50-liter pyrogen free water by dissolving the 1.5kg Citi-Taxime 250mg IM and later add propylene glycol, sodium chloride and sodium hydroxide. Clarification is required either the applied product is dry powder for injection or a solution for injection as evident from the detail	Firm has submitted the amended document in which cefepime HCl with L-arginine is mentioned as the only active ingredient. However, the information regarding the quantity of dry powder filled per vial has not been given. Further, the flow chart of manufacturing process submitted in the reply of section 3.2.P.3.3 is of ceftriaxone.

	manufacturing procedure given in section 3.2. P.3.3.	
6.	Provide complete analytical procedure used for routine testing of drug product since submitting the copy of USP monograph did not fulfil the requirement of section 3.2. P.5.2.	Firm again submit the copy of monograph of USP in section 3.2.P.5.2 and in section 3.2.P.4.2 submit the analytical procedure of cefotaxime injection.
7.	Analytical method of drug product verified in section 3.2.P.5.3 is different from that specified in USP monograph. Justify, for using different analytical method for verification studies.	Firm has not given the reply in response of this query.
8.	Scientific justification for not performing test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test during the batch release of the drug product	firm has submitted batch analysis report of three trail batches TRA-001, TRA-002, TRA-003 which were not the batch numbers of trial batches used for stability studies as evident from the submitted stability data sheets. Further, the test of completeness and clarity of solution, bacterial endotoxin test, testing of pH, water determination test and sterility test was not been included in batch analysis report nor given any justification. Furthermore, the firm submitted the same batch analysis report for cefepime 500mg injection and cefepime 1gm injection.
9.	Provide COA of primary / secondary reference standard including source and lot number in section 3.2. P.6.	Firm has submitted the reply in response of this query.
10.	Submit the stability data sheet of cefepime injection, since the submitted sheets are of ceftriaxone.	Firm stated that rectified and corrected stability data sheets are submitted.
11.	According to the document submitted in section 3.2. P.8 batch no. Cef-P-004, Cef-P-005and Cef-P-006 has been manufactured on 09-2021, while the dossier submitted in R&I of DRAP on 13th May,2022i.e. after 8 months of manufacturing of trial batches, clarification is required how you have submitted the stability data of real time study till 24month.	Firm stated that rectified and corrected stability data sheets are submitted. However, the firm submitted the raw data sheets of batch no. TC006-01, TC006-02, TC006-03.
12.	9. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. 10. Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point. 11. Provide Reference of previous approval of applications with	Firm has only submitted the chromatograms and 21 CFR audit trail report of instant product. Remaining documents has not been provided by the firm.

	stability study data of the firm (if any) 12. Documents for the procurement of API with approval from DRAP (in case of import). 13. Provide compliance Record of HPLC software 21CFR & audit trail reports on product testing. 14. Provide Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). 15. In-use stability studies of reconstituted injection is required along with proposed in-use storage statement and in-use shelf-life. 16. Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	

Decision of 321st meeting of Registration Board:

- Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.
- Analytical method verification report of drug substance performed by drug product manufacturer.
- Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.
- Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.
- Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.
- Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.
- Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.
- Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.
- Batch analysis report of all three trial batches, in which all the quality test should be included that are specify in USP monograph of Cefepime injection.
- Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
- Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.

Reply of the Firm:

Sr.no.	Decision of Registration Board	Response of Firm
1.	Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.	Firm submitted the specification and analytical procedure of drug substance by drug substance manufacturer instead from drug product manufacturer.
2.	Analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of

		conc of sample and standard solution recommended in the USP monograph.
3.	Long-term stability data of batch no. CEIV/B1203013 of drug substance till the claimed shelf life/re-test period.	submitted
4.	Compatibility study data of drug product with its diluent under the requirement of section 3.2.P.2.6.	submitted
5.	Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.	Not submitted
6.	Complete analytical procedure used for routine testing of applied drug product in section 3.2. P.5.2.	Submitted
7.	Analytical method verification report of assay testing of drug product ,in compliance of USP monograph of Cefepime Injection	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the USP monograph.
8.	Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.	Firm submitted the batch analysis report of three trial batches (TC007-001,TC007-002,TC007-003).
9.	• Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the form-6 bearing the dy.no. 6176 dated 16-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine. Firm submitted the commercial invoice bearing the dy.no. 6017/2021 DRAP dated 22-04-2021 and the stamp of concerned officer on the same document was of dated 22-04-2021, further the name of drug mentioned on the document was cefepime instead of cefepime L-Arginine.
10.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	As per the submitted raw data sheets and chromatograms it is evident that firm has not applied the chromatographic condition with reference to mobile phase gradient program, injection volume and sample conc. as recommended by USP.
11.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3	Not submitted

Decision: Deferred for submission of following:

- **Specifications as well as analytical method of the drug substance from the drug product manufacturer in section 3.2.S.4.1 and 3.2. S.4.2.**
- **Manufacturer will provide analytical method verification studies for drug substance by drug product manufacturer as per USP including specificity, accuracy and precision before the issuance of registration letter.**
- **Complete batch formula along with quantity of filled weight per vial in section 3.2.P.3.**
- **Analytical method verification report of assay testing of drug product, in compliance of USP monograph of Cefepime Injection.**
- **Clarification regarding the trial batches which were actually manufactured for the stability study of applied product.**

- **Clarification required for not applied the same chromatographic condition for assay testing of drug product as recommended by USP monograph of cefepime injection, as evident from the submitted raw data sheets and chromatograms of stability batches.**
- **Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3**

Cases of Form 5-F:

1919.	Name, / Marketing Authorization Holder address of Applicant	M/s Genome Pharmaceutical (Pvt.) Ltd Address: 16/I, Phase IV, Industrial Estate Hattar, KPK, Pakistan
	Name, address of Manufacturing site.	M/s Genome Pharmaceutical (Pvt.) Ltd Address: 16/I, Phase IV, Industrial Estate Hattar, KPK, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.25531 dated 14/09/2021
	Details of fee submitted	PKR 50,000/-: dated 03/05/2021
	The proposed proprietary name / brand name	Aqua-RET 15mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Tolvaptan.....15mg
	Pharmaceutical form of applied drug	White to Off white, round, biconvex, unscored, uncoated tablets
	Pharmacotherapeutic Group of (API)	Competitive antagonist at vasopressin V2 receptors
	Reference to Finished product specifications	Innovator
	Proposed Pack size	1x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Samsca 15 mg Tablet by Otsuka Pharmaceuticals, Registered in UK.
	For generic drugs (me-too status)	N.A
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted on 26-06-2020
	Name and address of API manufacturer.	Aurore Pharmaceuticals Private Limited. Unit-1, Plot Nos. 35, 36, 38 to 40, 49 to 51 Phase IV, IDA, Jeedimetla, Hyderabad – 500055, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system

		and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of drug substance is not present in any Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (TAAF190003, TAAF190004, TAAF190005)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Samsca 15 mg Tablet by Otsuka Pharmaceuticals performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the same brand that is Samsca 15 mg Tablet by Otsuka Pharmaceuticals in Acid media (pH 1.2), Acetate (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Aurore Pharmaceuticals Private Limited		
API Lot No.	TAAF190005		
Description of Pack (Container closure system)	Primary Container: 10 tablets are packed in Alu-Alu Foil Secondary Container: 1 blister of Alu-Alu Foil containing 10 film-coated tablets, packed in a printed carton along with a leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ART15-T001	ART15-T001	ART15-T001
Batch Size	3000 tab	3000 tab	3000 tab
Manufacturing Date	07-2020	07-2020	07-2020
Date of Initiation	21-07-2020	21-07-2020	21-07-2020
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Valsac 24mg/26 mg Tablets, Valsac 49mg/51 mg Tablets, Valsac 97mg/103 mg Tablets"which was conducted on 10-03-2020, and was presented in 295th meeting of Registration Board (8-11 June, 2020). Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP for Aurore Pharmaceuticals Issued by Drugs Control Administration Government of Telangana valid upto 11/12/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# 019) cleared by DRAP Peshawar Office, Pakistan dated 03-06-2020 specifying import 01 Kg (Batch# TAAF190005).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit differential fee for the registration of applied new drug product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP on 14th Sep, 2021.	Firm submitted the fee of Rs 25,000/- vide slip no. 84097079479 dated 15-09-2022.
2.	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.	Submitted
3.	Justify of including Isopropyl alcohol in the composition of formulation, since the given manufacturing method in section 3.2.P.3.3 did not the mentioned the use of IPA in any step.	Firm replied that it was consider the typographic error ,accordingly revised formulation has been submitted.
4.	Provide data of stability batches along with supporting documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Firm submitted the data of stability batches along with supporting documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.

Indication, Dosage & Administration of Innovator Brand Samsca:

Indication:

SAMSCA is a selective vasopressin V2-receptor antagonist indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia [serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

Important Limitations:

• Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA. • It has not been established that SAMSCA provides a symptomatic benefit to patients. Dosage & Administration: Patients should be in a hospital for initiation and re-initiation of therapy to evaluate the therapeutic response and because too rapid correction of hyponatremia can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. The usual starting dose for SAMSCA is 15 mg administered once daily without regard to meals. Increase the dose to 30 mg once daily, after at least 24 hours, to a maximum of 60 mg once daily, as needed to achieve the desired level of serum sodium. During initiation and titration, frequently monitor for changes in serum electrolytes and volume. Avoid fluid restriction during the first 24 hours of therapy. Patients receiving SAMSCA should be advised that they can continue ingestion of fluid in response to thirst. BOX Warning: *WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM See full prescribing information for complete boxed warning. • SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. • Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.* Therapeutic indications of Tolvaptan tablets submitted by the applicant: Aqua-ret 15 mg and 30mg tablets are manufactured according to the reference product Samsca manufactured by Otsuka Pharmaceutical Netherlands. The formulation of Aqua-ret 15 mg and 30 mg is according to the reverence product mentioned above. Samsca tablets are registered in 7.5 mg, 15 mg and 30 mg and available in 10's and 30's individual pack size. According to the summary of the product characteristic, this product is indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH). The treatment with Tolvaptan has to be initiated at a dose of 15 mg once daily. The dose may be increased to a maximum of 60 mg once daily as tolerated to achieve the desired level of serum sodium. The dose titration can be achieved from initial dose 15 mg using one tablet of 15mg and the maximum dose 60 mg using two tablets of 30 mg. The treatment with Tolvaptan to be initiated in hospital to closely monitor the dose titration and level of serum sodium. All the information for the dose titration and precautions are mentioned the patient leaflet provided with this product and enclose herewith. **Therapeutic Indication:** **Tolvaptan is a selective vasopressin V2-receptor antagonist and the applied product is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia [serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).** **Important Limitations:** **• Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA.** **• It has not been established that SAMSCA provides a symptomatic benefit to patients.** ***WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM See full prescribing information for complete boxed warning. • SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. • Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.***		
Decision: Approved with above therapeutic indication, limitations of use and box warning as recommended by the USFDA innovator product Samsca tablet.		
1920.	Name, / Marketing Authorization Holder address of Applicant	M/s Genome Pharmaceutical (Pvt.) Ltd Address: 16/I, Phase IV, Industrial Estate Hattar, KPK, Pakistan
	Name, address of Manufacturing site.	M/s Genome Pharmaceutical (Pvt.) Ltd

		Address: 16/I, Phase IV, Industrial Estate Hattar, KPK, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25924 dated 17-09-2021
	Details of fee submitted	PKR 75,000/-: dated 01/09/2021
	The proposed proprietary name / brand name	Aqua-RET 30mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each uncoated tablet contains: Tolvaptan.....30 mg
	Pharmaceutical form of applied drug	White to Off white, round, biconvex, unscored, uncoated tablets
	Pharmacotherapeutic Group of (API)	Competitive antagonist at vasopressin V2 receptors
	Reference to Finished product specifications	Innovator
	Proposed Pack size	1x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Samsca 30 mg Tablet by Otsuka Pharmaceuticals, Registered in UK.
	For generic drugs (me-too status)	N.A
	GMP status of the Finished product manufacturer	GMP certificate issued based upon inspection conducted on 26-06-2020
	Name and address of API manufacturer.	Aurore Pharmaceuticals Private Limited. Unit-1, Plot Nos. 35, 36, 38 to 40, 49 to 51 Phase IV, IDA, Jeedimetla, Hyderabad – 500055, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of drug substance is not present in any Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions:

		Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (TAAF190003, TAAF190004, TAAF190005)		
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is Samsca 30 mg Tablet by Otsuka Pharmaceuticals performing quality tests (Identification, Assay, Dissolution, and Uniformity of dosage form). CDP has been performed against the same brand that is Samsca 30 mg Tablet by Otsuka Pharmaceuticals in Acid media (pH 1.2), Acetate (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		Aurore Pharmaceuticals Private Limited		
API Lot No.		TAAF190005		
Description of Pack (Container closure system)		Primary Container: 10 tablets are packed in Alu-Alu Foil Secondary Container: 1 blister of Alu-Alu Foil containing 10 film-coated tablets, packed in a printed carton along with a leaflet.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		ART30-T001	ART30-T001	ART30-T001
Batch Size		3000 tab	3000 tab	3000 tab
Manufacturing Date		07-2020	07-2020	07-2020
Date of Initiation		28-07-2020	28-07-2020	28-07-2020
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Valsac 24mg/26 mg Tablets, Valsac 49mg/51 mg Tablets, Valsac 97mg/103 mg Tablets"which was conducted on 10-03-2020, and was presented in 295th meeting of Registration Board (8-11 June, 2020). Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. \ ✓ Audit trail reports were available and physically checked		

		Firm has adequate monitoring and controls for stability chambers. Software is installed for continuous monitoring of chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP for Aurore Pharmaceuticals Issued by Drugs Control Administration Government of Telangana valid upto 11/12/2020.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice (invoice# 019) cleared by DRAP Peshawar Office, Pakistan dated 03-06-2020 specifying import 01 Kg (Batch# TAAF190005).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit differential fee for the registration of applied new drug product, since the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA was published on 7th May 2021 while this application was received in R&I section of DRAP on 14th Sep, 2021.	Firm submitted the fee of Rs 25,000/- vide slip no. 84097079479 dated 15-09-2022.
2.	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.	Submitted
3.	Justify of including Isopropyl alcohol in the composition of formulation, since the given manufacturing method in section 3.2.P.3.3 did not the mentioned the use of IPA in any step.	Firm replied that it was consider the typographic error ,accordingly revised formulation has been submitted.
4.	Provide data of stability batches along with supporting documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	Firm submitted the data of stability batches along with supporting documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.

Indication, Dosage & Administration of Innovator Brand Samsca:

Indication:

SAMSCA is a selective vasopressin V2-receptor antagonist indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia [serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

Important Limitations:

• Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA.

• It has not been established that SAMSCA provides a symptomatic benefit to patients.

Dosage & Administration:

Patients should be in a hospital for initiation and re-initiation of therapy to evaluate the therapeutic response and because too rapid correction of hyponatremia can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death.

The usual starting dose for SAMSCA is 15 mg administered once daily without regard to meals. Increase the dose to 30 mg once daily, after at least 24 hours, to a maximum of 60 mg once daily, as needed to achieve the desired level of serum sodium. During initiation and titration, frequently monitor for changes in serum electrolytes and

volume. Avoid fluid restriction during the first 24 hours of therapy. Patients receiving SAMSCA should be advised that they can continue ingestion of fluid in response to thirst.
BOX Warning:
WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM See full prescribing information for complete boxed warning. • SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. • Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.

Therapeutic indications of Tolvaptan tablets submitted by the applicant:
Aqua-ret 15 mg and 30mg tablets are manufactured according to the reference product Samsca manufactured by Otsuka Pharmaceutical Netherlands. The formulation of Aqua-ret 15 mg and 30 mg is according to the reverence product mentioned above.
Samsca tablets are registered in 7.5 mg, 15 mg and 30 mg and available in 10's and 30's individual pack size. According to the summary of the product characteristic, this product is indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).
The treatment with Tolvaptan has to be initiated at a dose of 15 mg once daily. The dose may be increased to a maximum of 60 mg once daily as tolerated to achieve the desired level of serum sodium. The dose titration can be achieved from initial dose 15 mg using one tablet of 15mg and the maximum dose 60 mg using two tablets of 30 mg. The treatment with Tolvaptan to be initiated in hospital to closely monitor the dose titration and level of serum sodium.
All the information for the dose titration and precautions are mentioned the patient leaflet provided with this product and enclose herewith.

Decision: Approved with following therapeutic indication, limitations of use and box warning as recommended by the USFDA innovator product Samsca tablet:

Therapeutic Indication:
Tolvaptan is a selective vasopressin V2-receptor antagonist and the applied product is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia [serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

Important Limitations:
• Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with SAMSCA.
• It has not been established that SAMSCA provides a symptomatic benefit to patients.

WARNING: INITIATE AND RE-INITIATE IN A HOSPITAL AND MONITOR SERUM SODIUM See full prescribing information for complete boxed warning. • SAMSCA should be initiated and re-initiated in patients only in a hospital where serum sodium can be monitored closely. • Too rapid correction of hyponatremia (e.g., >12 mEq/L/24 hours) can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. In susceptible patients, including those with severe malnutrition, alcoholism or advanced liver disease, slower rates of correction may be advisable.

1921.	Name, / Marketing Authorization Holder address of Applicant	M/s. Ophth Pharma (Pvt.) Ltd. Plot no. 241, Sector 24, Korangi Industrial Area Karachi.
	Name, address of Manufacturing site.	M/s. Ophth Pharma (Pvt.) Ltd. Plot no. 241, Sector 24, Korangi Industrial Area Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No.30262 dated 05-11-2021
	Details of fee submitted	PKR 30,000/- dated 19/01/2021
	The proposed proprietary name / brand name	Carmeze Eye drops
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Carboxymethyl cellulose sodium…10mg
	Pharmaceutical form of applied drug	Clear, colorless to slight yellow viscous solution and packed in unit carton along with leaflet
	Pharmacotherapeutic Group of (API)	Ophthalmic lubricant
	Reference to Finished product specifications	BP
	Proposed Pack size	10ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved CELLUVISC® 1% w/v EYE DROPS, SOLUTION (Carmellose Sodium).
	For generic drugs (me-too status)	Optheez drops of M/s. Barrett & Hodgson Pakistan (Pvt.) Ltd. Reg.no.093070
	GMP status of the Finished product manufacturer	GMP certificate issued dated 29th sep,2021 based upon inspection conducted on 27th sep, 2021,valid for 2 years.
	Name and address of API manufacturer.	M/s. Anhui Sunhere Pharmaceutical Excipients Co. Ltd. No.2 Hebin Road, Economic Development Zone,Huainan,Anhui,China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of drug substance present BP Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (110403,110404,110405)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the comparator product that is Optheez drops of M/s. Barrett & Hodgson Pakistan (Pvt.) Ltd. Reg.no.093070 performing quality tests (Identification, ,pH, osmolality).
	Analytical method validation/verification of product	Method verification studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s. Anhui Sunhere Pharmaceutical Excipients Co. Ltd. No.2 Hebin Road, Economic Development Zone,Huainan,Anhui,China		
API Lot No.	110405		
Description of Pack (Container closure system)	Primary Container: 10ml plastic bottle Secondary Container: packed in a printed carton along with a leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 35% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Real Time: 0, 2, 4, 6 ,12,18,24(Months) Accelerated : 0, 3, 6 (Months)		
Batch No.	Tb-101	Tb-102	Tb-103
Batch Size	1 LITRE	1 LITRE	1 LITRE
Manufacturing Date	11-2017	11-2017	11-2017
Date of Initiation	03-11-2017	03-11-2017	03-11-2017
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm submitted the letter related to submission of sample of carboxymethyl cellulose sodium to M/s. Ophth Pharma from Rasheedsons for evaluation purpose.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Justify the finished product specifications as "USP specifications" since the drug product monograph is only available in BP Pharmacopoeia. Revise your specifications along with submission of requisite fee.	Firm submitted the revised finished product specification from USP specification to BP specification in section 3.2.P.5., however in module 1 section 1.5.6 firm again claimed USP specification for drug product.
2.	Submit specifications as well as analytical method of the drug substance from the drug product manufacturer as well as drug substance manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Firm only submit the copy of USP monograph of carboxymethyl cellulose sodium. Specification and analytical procedure by drug substance manufacturer has not been submitted by the firm.
3.	Submit data in section 3.2.S.4.3 as per the guidance document approved by Registration	Firm submitted the analytical method verification report without any detail regarding the assay procedure

	Board which specifies that "Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted" Further specify how the testing of drug substance was carried out without performing verification studies.	which has been verified and clarity related quantification data of precision and accuracy parameter (either the quantify amount was of carboxymethyl cellulose sodium or only the sodium content)
4.	• Provide details including batch number, expiry date and name of manufacturer of the product along with pharmaceutical equivalence was performed. • Perform all the test which are included in the BP monograph of carmellose sodium ophthalmic drops to establish pharmaceutical equivalence with the reference product.	Firm submitted the pharmaceutical equivalence report performed against the optheez eye drop of M/s. Barrett & Hodgson and only identification and pH and osmolality test has been included in the report. Assay has not performed while the performance of pharmaceutical equivalence.
5.	According to the batch analysis report of finished product you have adopted in-house specification for the testing of drug product since the monograph of applied product is present in BP pharmacopeia. Revise the specification of drug product in compliance to BP monograph and accordingly submit the revised analytical procedure and verification report.	Firm submitted the analytical verification report from which it is evident that the performance of accuracy parameter did not cover the range of conc of sample and standard solution recommended in the BP monograph.
6.	Provide COA of the reference standard / working standard actually used in the analysis of drug product in section 3.2.P.6.	Firm submitted the COA of working standard with USP claim, while the claimed specification of finished product is BP.
7.	Provide detail about the container closure system and performance report of water loss study	Firm informed that the primary container closure system is plastic bottle and did not submit the report of water loss study.
8.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the letter related to submission of sample of carboxymethyl cellulose sodium to M/s. Ophth Pharma from Rasheedsons for evaluation purpose.
9.	Provide data of stability batches properly arranged and supported by respective documents including analytical report / COA, raw data sheet and respective chromatograms separately for each time point.	As per the submitted raw data sheets it is evident that firm has not performed the assay testing as recommended by BP monograph with reference to sample and standard conc.
10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.3.	Submitted.

Decision: Deferred for the submission of following:

- **Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**
- **Submit detailed analytical method of the drug substance from the drug product manufacturer as well as drug substance manufacturer in section 3.2.S.4.2.**

- **Performed verification study on the assay method of drug substance in accordance with USP monograph by drug product manufacturer.**
- **Pharmaceutical Equivalence report against the innovator/reference product and performed all the quality test as recommended by the BP monograph.**
- **Analytical method verification report of drug product including specificity, accuracy and precision (repeatability) parameter.**
- **Submitted COA of working standard is of USP grade, whereas drug product specifications have been claimed as per BP monograph.**
- **Water loss study of drug product, since the primary container of drug product is LDPE bottles.**
- **API procurement document including copy of commercial invoice attested by AD (I&E) DRAP.**
- **Scientific justification for non-compliance of BP monograph while performing the assay testing of drug product during stability studies as evident from submitted raw data sheets.**

Previously Deferred Cases of Form 5-F.

1922.	Name, address of Applicant / Marketing Authorization Holder	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 11065 dated 27/08/2021
	Details of fee submitted	PKR 75,000/-: dated 06/07/2021
	The proposed proprietary name / brand name	BISTIN 2.5mg/ml Oral Solution
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Bilastine……2.5mg
	Pharmaceutical form of applied drug	Clear colorless to slightly colored Oral Solution
	Pharmacotherapeutic Group of (API)	Antihistamines ATC Code: RO6AX29
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	60ml & 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bilaxten 2.5mg/ml oral solution M/s. FAES FARMA, SA Maximo Aguirre, 1448940 – Leioa Spain Approved.
	For generic drugs (me-too status)	Not applicable
	GMP status of the Finished product manufacturer	GMP certificate issued dated: 11-08-2020
	Name and address of API manufacturer.	Virupaksha Organics Limited Address: Survey No. 10 Gaddapototharam Village Jinnaram, Mandal, Sangareddy District – 502319, Telangana, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ABSTC0120001, ABSTC0120002, ABSTC0120003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, individual impurity and total impurity, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	It may please be noted that despite of our contacting M/s. Menarini Farmaceutica Internazionale SRL as well as local distributor, we could not obtain samples for conducting Pharmaceutical Equivalence. Due to the above fact w.r.t. its procurement, we are unable to perform Pharmaceutical Equivalence but despite of that we have considered and ensured that our formulation comply with the innovator & all our quality tests i.e. Identification, Assay, pH, Preservatives test, Degradation products and Microbial Enumeration Test comply the references/general guidelines and validated as per USP guidelines which ensures the quality and safety of our product CDP not applicable
	Analytical method validation/verification of product	Method validation studies have submitted including Linearity, Accuracy, Precision including Repeatability & Intermediate Precision, Robustness and Specificity.

STABILITY STUDY DATA	
Manufacturer of API	Virupaksha Organics Limited, Telangana India
API Lot No.	ABSNC1119001
Description of Pack (Container closure system)	Amber Glass Bottle packed in unit carton (60ml & 120ml)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 65% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1,2,3,4 & 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	4 Liters	4 Liters	4 Liters
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	03-4-2020	03-4-2020	03-4-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Reference of our last onsite panel inspection for instant dosage form conducted during last three years LAGITA Double Action Suspension (Sodium Alginate + Sodium Bicarbonate + Calcium Carbonate) 500mg + 213mg + 325mg on 30th January 2020 The inspection report confirms following points The HPLC software is 21CFR Compliant 1. Audit trail on the testing reports is available. 2. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. 3. Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 5884/E1/2018 issued by DRUGS CONTROL ADMINISTRATION Government of Telangana valid till 27/03/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (Invoice# AEX/085/2019-20 dated 27th November 2019 with received quantity i.e. 400gm) for the purchase of Bilastine from M/s Virupaksha Organics Ltd. India with attestation of DRAP dated 03-12-2019
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

Sr.no.	Shortcomings/Deficiencies	Response of the Firm
1.	Provide Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin since the submitted GMP certificate was valid till 2021.	Firm has submitted the copy of GMP certificate of drug substance manufacturer i.e. M/s. Virupaksha Organic Limited, Telangana state which is valid up till 29/01/2022.

2.	Justification is required for not performing the powder x-ray diffraction test by drug product manufacturer to confirm the polymorphic state of drug substance, since the bilastine has three different polymorphic forms. Further, the test has been included in the COA of the drug substance manufacturer.	Since, the testing facility of P-XRD is not available in Pakistan therefore we rely on drug substance manufacturer COA.
3.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Firm submitted preservative effectiveness studies of drug product.
4.	Justification is required for not performing compatibility studies of excipient with active ingredient, since the solubilizing agent of innovator is betadex and you have using β-Cyclodextrin sulfobutylether, sodium salt as a solubilizer.	Firm submitted the API- Excipient compatibility study report of bilastine oral solution.
5.	Provide data of pharmaceutical equivalence against the innovator product to justify your formulation development as per the requirement of section 3.2. P.2.2.1.	Firm submitted the reply that the reference product is not available in Pakistan, they have tried to arrange it from the country of origin but unfortunately not succeeded.

Decision of 321st meeting of Registration Board:
Deferred for submission of pharmaceutical equivalence report against the innovator drug product.

Response of the Firm:
Firm submitted the Pharmaceutical equivalence report performed against the reference product Bilaxten 2.5mg/ml oral solution of M/s. FAES FARMA, S.A. Maximo Aguirre, 1448940 – Leioa, Spain and Batch no. 3124, Expiry date june-2024 performed quality test (pH, weight/ml, Assay, quantification of methyl paraben, propyl paraben, Microbial enumeration test.)

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

Agenda of Evaluator PEC-XVI.

Case No.01
A: REGISTRATION HUMAN (NEW LICENSE) FORM-5F

1923.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.27405 dated 27-09-2022
	Details of fee submitted	PKR 30,000/-: Slip No. 45811149 dated 21/09/2022
	The proposed proprietary name / brand name	Pinabax 5mg tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban ……..……5mg
	Pharmaceutical form of applied drug	Red, oval tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Anticoagulant, Cardiovascular, Factor Xa Inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Eliquis Tablets 5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute, USFDA Approved.
	For generic drugs (me-too status)	Apixaget 5mg Tablet by M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 105248
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Name and address of API manufacturer.	**API-Apixaban:** CHANGZHOU PHARMACEUTICAL FACTORY. No.518 Laodong East Road, Changzhou, Jiangsu Province 213018, **China.**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity AG-A, AG-G, AG-C, AG-4, AG-II, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Apixaban:** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data conditions are: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Eliquis Tablets 5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Eliquis Tablets 5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Linearity, Range, Accuracy, Precision, specificity and/or selectivity, Repeatability, Intermediate precision Robustness, Solution Stability, and LOD & LOQ.

STABILITY STUDY DATA

Manufacturer of API	**API-Apixaban** Changzhou Pharmaceutical Factory.		
API Lot No.	**Apixaban** ZSAP211001		
Description of Pack (Container closure system)	Alu. Alu. Blister strips of 3x10's Tablets packed in a printed unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T024	T034	T035
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	27-04-2022	27-04-2022	27-04-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate Jiangsu Changzhou Pharmaceutical Quality Association valid till 15/09/2025.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Not Provided**
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software CRF 21 Compliance is not provided, However firm has submitted audit trail reports.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Provided

Remarks of Evaluator:

Sr#	Section	Observation	Reply of firm vide dairy No.34064 dated 25-11-2022
01	**1.6.5**	Copy of GMP certificate Jiangsu Changzhou Pharmaceutical Quality Association is provided. GMP of Drug Control/Administration of country of origin is required.	Firm has submitted copy of GMP GMP certificate Jiangsu Changzhou Pharmaceutical Quality Association. Firm also submitted copy of Drug Manufacturing License of API manufacturer issued by provincial Drug and Food Authority of China.
02	**2.3.P.2.1.2**	Firm has mentioned that acceptable limit of Croscarmellose Sodium is 2-5 % w/w , however firm has utilized 9.00 % of Croscarmellose sodium per tablet as disintegrant , which needs clarification/justification.	Firm stated that they decided to use 9 % Croscarmellose Sodium in Apixaban formulation development to improve the dissolution profile of Apixaban. In case of initial formulation, where 5 % Croscarmellose was used, the dissolution results did not meet the required specifications, so we decided to add 9 % to improve the dissolution as the results of which dissolution profile was improved. Croscarmellose sodium is mainly used as a disintegrent in oral pharmaceutical formulations and is generally regarded as essentially nontoxic and nonirritant material. In U.K, Croscarmellose sodium is accepted for use in dietary supplement therefore use of Croscarmellose more than 5 % is safe. WHO has not specified an acceptable daily intake for the related substance carboxymethyl cellulose sodium ,used as food additive ,since the levels necessary to achieve a desired effect were not considered sufficient to be a hazard to health .we have also studied various pharmaceutical formulations papers and found that the use limit may be extended up to 25 %
03	**2.3.P.5.2**	• The testing method specifications/conditions mentioned for Dissolution test does not mentioned 0.05% Sodium lauryl Sulphate to be added along with 6.8 P.H Sodium Phosphate Buffer at 37 C, USP type II apparatus at 75 rpm. 0.05 % SLS is mentioned in release and stability study specification /conditions for conducting dissolution test mentioned in USFDA pharmaceutical review of Innovator product. Clarification is needed. • The chromatographic system used to conduct dissolution assay mentioned UV -242nm whereas for conducting Assay test HPLC is used with detector at UV-280nm. Clarification is needed.	• Firm has stated that they have adopted dissolution of Apixaban Tablet from FDA dissolution data base in which addition of 0.05 % SLS is recommended in P.H 6.8 sodium buffer dissolution media, Same conditions followed throughout the stability testing and same already mentioned in specification and testing method. • The chromatographic system is used to conduct both dissolution & Assay test is 28 nm, same mentioned in chromatographic conditions of dissolution & Assay.

04	**3.2.P.2**	Comparative dissolution profile study is conducted with Eliquis Tablets 5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute's , However the dissolution medium used does not mentioned addition of 0.05 % SLS which has been mentioned in Biopharmaceuticals review of USFDA for innovator product tablet Eliquis .Clarification is needed.	Revised Comparative dissolution profile study as per FDA with the addition of 0.05 % SLS is performed and submitted
05	**3.2.P.8.3**	• Documents for the procurement of API with approval from DRAP (in case of import). • COA of Same Batch of API conducted by API manufacturer and subsequently finished product manufacturer. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated	Firm has provided copy of commercial invoice# CYI21376 attested by AD I&E DRAP dated 29-11-2021 for import of 0.1Kg of Apixaban (Batch# ZSAP211001) Not Provided Provided

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board directed the firm to optimize the formulation for quantity of Crosscarmellose within permissible limits as per Handbook of Pharmaceutical excipients/recommendations of reference regulatoruy authorities, for commercial batches.**

1924.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25823 dated 13/09/2022
	Details of fee submitted	PKR30,000/-:Slip no.18805099 dated 02/09/2022
	The proposed proprietary name / brand name	Dapamax 5mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin……..….5mg.
	Pharmaceutical form of applied drug	Blue film coated round tablet plain from both sides.
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors.
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	FARXIGA Tablets 5mg by ASTRAZENECA AB, FDA, US Approved.
	For generic drugs (me-too status)	Dapa 5mg Tablet by Hilton Pharma (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Name and address of API manufacturer.	**API: Dapagliflozin Propanediol Monohydrate** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**API: Dapagliflozin Propanediol Monohydrate** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence studies with reference product i.e., Dapa-5mg Tablet by Hilton Pharma (Pvt.) Ltd. CDP has been performed against the same brand that is Dapa-5mg Tablet by Hilton Pharma (Pvt.) Ltd.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy,

		precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.	

STABILITY STUDY DATA

Manufacturer of API	**API: Dapagliflozin Propanediol Monohydrate** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China		
API Lot No.	**API: Dapagliflozin Propanediol Monohydrate.** DG-20190116-D01-DG06-01		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-023	T-031	T-032
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	28-04-2022	28-04-2022	28-04-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	License Number: LIAO 20150233 Issue Date: May 18, 2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**API: Dapagliflozin Propanediol Monohydrate.** • Permission to import different APIs including Dapagliflozin for the purpose of test/analysis and stability studies is granted. • License No.3942/21/DRAP-AD-CD(I&E) dated 10/12/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software CRF 21 Compliance is not provided, However firm has submitted audit trail reports.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator:

Sr#	Section	Observation	Reply of firm vide dairy No.34075 dated 25-11-2022
i.	**3.2.P.8.3**	• Documents for the procurement of API with approval from DRAP (in case of import). are not provided	• Copy of commercial invoice# HN20211027-A attested by AD DRAP I&E 10-12-2021 submitted.

		• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not provided.	• Submitted

Decision: Approved with innovator's specifications.

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

1925.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 25821 dated 13/09/2022
	Details of fee submitted	PKR30,000/-:Slip No.7476231899 dated 02/09/2022
	The proposed proprietary name / brand name	Dapamax 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin……..….10mg.
	Pharmaceutical form of applied drug	White color film coated round tablet plain from both sides.
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors.
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	2×7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA Tablets 10mg by ASTRAZENECA AB, FDA, US Approved.
	For generic drugs (me-too status)	Dapa 10mg Tablet by Hilton Pharma (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Name and address of API manufacturer.	**API: Dapagliflozin Propanediol Monohydrate** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning

		Province -123000, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**API: Dapagliflozin Propanediol Monohydrate** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence studies with reference product i.e., Dapa-10mg- Tablet. CDP has been performed against the same brand that is Dapa-10mg Tablet by Hilton Pharma (Pvt.) Ltd.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.

STABILITY STUDY DATA

Manufacturer of API	**API: Dapagliflozin Propanediol Monohydrate** M/s. Fuxin Long Rui Pharmaceutical Co. Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China
API Lot No.	**API: Dapagliflozin Propanediol Monohydrate.** DG-20190116-D01-DG06-01
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×7's)
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-017	T-027	T-028
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	28-04-2022	28-04-2022	28-04-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	License Number: LIAO 20150233 Issue Date: May 18, 2020 valid up to 20-12-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**API: Dapagliflozin Propanediol Monohydrate.** • Permission to import different APIs including Dapagliflozin for the purpose of test/analysis and stability studies is granted. • License No.3942/21/DRAP-AD-CD(I&E) dated 10/12/2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software CRF 21 Compliance is not provided, However firm has submitted audit trail reports.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr#	Section	Observation	Reply of firm vide dairy No.34075 dated 25-11-2022
i.	**3.2.P.8.3**	• Documents for the procurement of API with approval from DRAP (in case of import). are not provided • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not provided.	• Submitted • Not submitted

Decision: Approved with innovator's specifications.

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

1926.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd.

		Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26386 dated 19/09/2022
	Details of fee submitted	PKR 30,000/-:Slip No7134203052 dated 07/09/2022
	The proposed proprietary name / brand name	Rosupro 5mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin as Calcium…….5mg
	Pharmaceutical form of applied drug	White Color, Oval shape, film coated tablet, plain, on both sides.
	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitors (statins).
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Crestor Tablets 5mg, IPR PHARMACEUTICALS INC, USFDA Approved.
	For generic drugs (me-too status)	Rovista 5mg Tablet by Getz Pharma Pakistan (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Name and address of API manufacturer.	**API: Rosuvastatin Calcium** M M/s Glenmark Life Sciences Limited Address: 4th Floor, OIA House, 470, Cardinal Gracious Road, Andheri East Mumbai 400099, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**API: Rosuvastatin Calcium** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 25˚C ± 2˚C / 60% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence studies with reference product i.e., Rovista 5mg Tablet by Getz Pharma Pakistan (Pvt.) Ltd. CDP has been performed against the same brand that is Rovista 5mg Tablet by Getz Pharma Pakistan (Pvt.) Ltd.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.

STABILITY STUDY DATA

Manufacturer of API	**API: Rosuvastatin Calcium** M/s Glenmark Life Sciences Limited Address: 4th Floor, OIA House, 470, Cardinal Gracious Road,		
API Lot No.	**API: Rosuvastatin Calcium.** Batch No. 84210667		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T002	T005	T006
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	12-04-2022	12-04-2022	12-04-2022
No. of Batches	03		

Administrative Portion

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate No: 6097474 Issue Date: Jan 13, 2021 (Expired) License No: MH/102854 Issue Date: 01/01/2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**API: Rosuvastatin Calcium.** • Permission to import different APIs including Rosuvastatin calcium for the purpose of test/analysis and stability studies is granted. • License No.3940/21/DRAP-AD-CD(I&E) dated 10/12/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software CRF 21 Compliance is not provided, However firm has submitted audit trail reports.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr#	Section	Observation	Reply of firm vide dairy No.33871 dated 24-11-2022
i	1.6.5	Provided copy of GMP certificate of API manufacturer is expired.	Firm has provided copy of GMP certificate No. 6103654 validity period up to 26-12-2022
ii	2.3.S.7.1	Firm has provided API stability study data (Real time) which is conducted by API manufacturer at 25 C temperature and 60 % relative humidity. Stability Study data conducted at zone IV A is required.	Firm has provided copy of API stability study data of 3 batches conducted at Temperature 30 C and relative humidity of 75 %.
iii	2.3.S.4.3	Firm is requested to provide details of column utilized to conduct Pharmacopoeial Enantiomeric impurity testing of Rosuvastatin Calcium API and also mention provision/availability of L 107 chiral column in this regard as the same is not evident form the provided data.	Firm has submitted that for the testing of Enantiomeric purity of Rosuvastatin calcium USP monograph recommend the 4.6-mm × 15-cm; 5-µm packing L107. Firm has utilized • Lux® 5-µm cellulose-3 LC Column 150 x 4.6mm part No: 00F-4493-E0 of Phenomenex for testing the Enantiomeric purity of Rosuvastatin calcium *(ref: USP Chromatographic Column & picture of column box is attached)* • Firm has submitted copy of import Invoice & Packing list is also attached for reference
iv	2.3.P.2.1.2	Firm has submitted that Crospovidone acceptable range is 2-5 % however they have utilized 6 % in their formulation also the provided acceptable range of Calcium Phosphate tribasic is 10-20 % w/w however 25 % is utilized. Justification of utilization of excipients out of acceptable range is required.	Firm has submitted that • Calcium Phosphate, Tribasic is a diluent and which can be used from 10-90. However, 10-20 was a typo error • Crospovidone is a cross-linked, water-insoluble super disintegrant. It is usually incorporated dry in the running powder of a tablet formulation, but it can also be processed by wet and dry granulation methods. Generally, crospovidone is used at the concentration of 2%–5% w/w (Rowe et al., 2009). Crospovidone levels higher than 8% of tablet weight produces weaker tablets with a faster disintegration Similar to sodium starch glycolate, crospovidone disintegrates tablets mainly by swelling, with little tendency to form gels. Crospovidone can also be used for solubility enhancement of poorly soluble drugs in the process of evaporation. This

			process enables the drug adsorption onto crospovidone in the presence of a suitable solvent, and the solvent is then evaporated to provide a solid mixture with a faster drug dissolution rate. Crospovidone is used in oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material. Short term animal toxicity studies have shown no adverse effects associated with crospovidone.
v	2.3.P.5.1	Firm has calculated assay of Rosuvastatin in finished tablet utilizing formula which seems different from the pharmacopoeial calculation for assay, justification of adopted formula in comparison to pharmacopoeial formula is required	Firm has submitted that as per USP appended formula is mentioned for the calculation of assay content Result = (*rU*/*rS*) × (*CS*/*CU*) × [*M* × (*Mr1*/*Mr2*)] × 100 PHARMACOPEIAL CALCULATION **Calculation of std concentration** Wt of standard/20 x 5/200 x potency (%on as is basis)/100 x 1000 19.83/20 x 5/200 x 94.98/100 x 1000 Cs= 23.54 µg/ml **Assay**= (899967/812102.8) x (23.54/25) x [2 x (481.54 /1001.14)] x 100 Result= 100.38% In our testing method appended formula is used to calculate the assay content IN-HOUSE CALCULATION Area of spl. x Wt. of std. x 5 x P (% as is basis) x 200 x 50 x Avg.Wt.x factor (0.962) / Area of std. x 20 x 200 x 100 x Wt. of spl. x 5 = mg Rosuvastatin / Tablet % = Rosuvastatin (mg/Tablet) x 100 Label Claim (5mg) = % Rosuvastatin 899967 x 19.83 x 5 x 94.98 x 200 x 50 x 196.39 x 0.962 812102.8 x 20 x 200 x 100 x 1963.9 x 5 = 5.02mg Rosuvastatin / Tablet Result = 100.40% USP used the concentration of Standard and sample preparation, while our in-house calculation used the accurate weight and dilution of both so there is no chance of error in results, moreover either used pharmacopoeial formula or in-house, results were same as mentioned in above calculation.
vi	3.2.P.8.3	• Documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Firm has provided copy of Form-6, License No.3940/21/DRAP-AD-CD(I&E) dated 10/12/2021 for import on .60 kg of Rosuvastatin Calcium. • Firm has also provided copy of invoice No Nil dated Nil for import of .06 kg of Rosuvastatin Calcium cleared from DRAP khi office.

Decision: Approved with USP specifications.

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

1927.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd.

	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26385 dated 19/09/2022
	Details of fee submitted	PKR 30,000/-:Slip No349245090 dated 07/09/2022
	The proposed proprietary name / brand name	Rosupro 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin as Calcium…….10mg
	Pharmaceutical form of applied drug	Blue color and oval shaped film coated tablet plain on both sides.
	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitors (statins).
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Crestor Tablets 10mg, IPR PHARMACEUTICALS INC, USFDA Approved.
	For generic drugs (me-too status)	Rovista 10mg Tablet by Getz Pharma Pakistan (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Name and address of API manufacturer.	**API: Rosuvastatin Calcium** M/s Glenmark Life Sciences Limited Address: 4th Floor, OIA House, 470, Cardinal Gracious Road, Andheri East Mumbai 400099, Maharashtra, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its

		validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**API: Rosuvastatin Calcium** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence studies with reference product i.e., Crestor 10mg Tablet by AstraZeneca. CDP has been performed against the same brand that is Crestor 10mg Tablet by AstraZeneca.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.

STABILITY STUDY DATA

Manufacturer of API	**API: Rosuvastatin Calcium** M/s Glenmark Life Sciences Limited Address: 4th Floor, OIA House, 470, Cardinal Gracious Road.		
API Lot No.	**API: Rosuvastatin Calcium.** Batch No. 84210667		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T009	T013	T014
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	03-2022	04-2022	04-2022
Date of Initiation	11-04-2022	12-04-2022	12-04-2022
No. of Batches	03		

Administrative Portion

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

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate No: 6097474 Issue Date: Jan 13, 2021 License No: MH/102854 Issue Date: 01/01/2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**API: Rosuvastatin Calcium.** • Permission to import different APIs including Rosuvastatin for the purpose of test/analysis and stability studies is granted. • License No.3940/21/DRAP-AD-CD(I&E) dated 10/12/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software CRF 21 Compliance is not provided, However firm has submitted audit trail reports.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr#	Section	Observation	Reply of firm vide dairy No.33871 dated 24-11-2022
i	1.6.5	Provided copy of GMP certificate of API manufacturer is expired.	Firm has provided copy of GMP certificate No. 6103654 validity period up to 26-12-2022
ii	2.3.S.7.1	Firm has provided API stability study data (Real time) which is conducted by API manufacturer at 25 C temperature and 60 % relative humidity. Stability Study data conducted at zone IV A is required.	Firm has provided copy of API stability study data of 3 batches conducted at Temperature 30 C and relative humidity of 75 %.
iii	2.3.S.4.3	Firm is requested to provide details of column utilized to conduct Pharmacopoeial Enantiomeric impurity testing of Rosuvastatin Calcium API and also mention provision/availability of L 107 chiral column in this regard as the same is not evident form the provided data.	Firm has submitted that for the testing of Enantiomeric purity of Rosuvastatin calcium USP monograph recommend the 4.6-mm × 15-cm; 5-µm packing L107. Firm has utilized • Lux® 5-µm cellulose-3 LC Column 150 x 4.6mm part No: 00F-4493-E0 of Phenomenex for testing the Enantiomeric purity of Rosuvastatin calcium *(ref: USP Chromatographic Column & picture of column box is attached)* • Firm has submitted copy of import Invoice & Packing list is also attached for reference
iv	2.3.P.2.1.2	Firm has submitted that Crospovidone acceptable range is 2-5 % however they have utilized 6 % in their formulation also the provided acceptable range of Calcium Phosphate tribasic is 10-20 % w/w however 25 % is utilized. Justification of utilization of excipients out of acceptable range is required.	Firm has submitted that • Calcium Phosphate, Tribasic is a diluent and which can be used from 10-90. However, 10-20 was a typo error • Crospovidone is a cross-linked, water-insoluble super disintegrant. It is usually incorporated dry in the running powder of a tablet formulation, but it can also be processed by wet and dry granulation methods. Generally, crospovidone is used at the concentration of 2%–5% w/w (Rowe et al., 2009). Crospovidone levels higher than 8% of tablet weight produces weaker tablets with a faster disintegration Similar to sodium starch glycolate, Crospovidone disintegrates tablets mainly by swelling, with little tendency to form gels. Crospovidone can also be used for solubility enhancement of poorly soluble drugs in the process of evaporation. This

			process enables the drug adsorption onto Crospovidone in the presence of a suitable solvent, and the solvent is then evaporated to provide a solid mixture with a faster drug dissolution rate. Crospovidone is used in oral pharmaceutical formulations and is generally regarded as a nontoxic and nonirritant material. Short term animal toxicity studies have shown no adverse effects associated with crospovidone.
v	2.3.P.5.1	Firm has calculated assay of Rosuvastatin in finished tablet utilizing formula which seems different from the pharmacopoeial calculation for assay, justification of adopted formula in comparison to pharmacopoeial formula is required	Firm has submitted that as per USP appended formula is mentioned for the calculation of assay content Result = (*rU*/*rS*) × (*CS*/*CU*) × [*M* × (*Mr1*/*Mr2*)] × 100 PHARMACOPEIAL CALCULATION **Calculation of std concentration** Wt of standard/20 x 5/200 x potency (%on as is basis)/100 x 1000 19.83/20 x 5/200 x 94.98/100 x 1000 Cs= 23.54 µg/ml **Assay**= (899967/812102.8) x (23.54/25) x [2 x (481.54 /1001.14)] x 100 Result= 100.38% In our testing method appended formula is used to calculate the assay content IN-HOUSE CALCULATION Area of spl. x Wt. of std. x 5 x P (% as is basis) x 200 x 50 x Avg.Wt.x factor (0.962) / Area of std. x 20 x 200 x 100 x Wt. of spl. x 5 = mg Rosuvastatin / Tablet % = Rosuvastatin (mg/Tablet) x 100 Label Claim (5mg) = % Rosuvastatin 899967 x 19.83 x 5 x 94.98 x 200 x 50 x 196.39 x 0.962 812102.8 x 20 x 200 x 100 x 1963.9 x 5 = 5.02mg Rosuvastatin / Tablet Result = 100.40% USP used the concentration of Standard and sample preparation, while our in-house calculation used the accurate weight and dilution of both so there is no chance of error in results, moreover either used pharmacopoeial formula or in-house, results were same as mentioned in above calculation.
vi	3.2.P.8.3	• Documents for the procurement of API with approval from DRAP (in case of import). • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Firm has provided copy of Form-6, License No.3940/21/DRAP-AD-CD(I&E) dated 10/12/2021 for import on .60 kg of Rosuvastatin Calcium. • Firm has also provided copy of invoice No Nil dated Nil for import of .06 kg of Rosuvastatin Calcium cleared from DRAP khi office.

Decision: Approved with USP specifications.

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

1928.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd.

	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26384 dated 19/09/2022
	Details of fee submitted	PKR 30,000/-:Slip No 21661479808 dated 07/09/2022
	The proposed proprietary name / brand name	**Rosupro 20mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin as Calcium……20mg
	Pharmaceutical form of applied drug	Brown color and oval shaped film coated tablet plain on both sides.
	Pharmacotherapeutic Group of (API)	HMG-CoA reductase inhibitors (statins).
	Reference to Finished product specifications	USP Specs
	Proposed Pack size	1 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Crestor Tablets 20mg, IPR PHARMACEUTICALS INC, USFDA Approved.
	For generic drugs (me-too status)	Rovista 20mg Tablet by Getz Pharma Pakistan (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Name and address of API manufacturer.	**API: Rosuvastatin Calcium** M M/s Glenmark Life Sciences Limited Address: 4th Floor, OIA House, 470, Cardinal Gracious Road, Andheri East Mumbai 400099, Maharashtra, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation,

		batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**API: Rosuvastatin Calcium** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence studies with reference product i.e., Crestor 10mg Tablet by AstraZeneca. CDP has been performed against the same brand that is Crestor 10mg Tablet by AstraZeneca.
	Analytical method validation/verification of product	Method validation studies have submitted including System Suitability, Linearity, Accuracy, precision, Specificity, Limit of Quantification, Limit of Detection, Robustness.

STABILITY STUDY DATA

Manufacturer of API	**API: Rosuvastatin Calcium** M/s Glenmark Life Sciences Limited Address: 4th Floor, OIA House, 470, Cardinal Gracious Road,		
API Lot No.	**API: Rosuvastatin Calcium.** Batch No. 84210667		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T010	T015	T016
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	11-04-2022	11-04-2022	11-04-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate No: 6097474 Issue Date: Jan 13, 2021 License No: MH/102854 Issue Date: 01/01/2019

3.	Documents for the procurement of API with approval from DRAP (in case of import).	**API: Rosuvastatin Calcium.** • Permission to import different APIs including Rosuvastatin for the purpose of test/analysis and stability studies is granted. • License No.3940/21/DRAP-AD-CD(I&E) dated 10/12/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software CRF 21 Compliance is not provided, However firm has submitted audit trail reports.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Decision: Approved with USP specifications.

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

Decision:

1929.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd. Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No.27640 dated 29/09/2022
	Details of fee submitted	PKR 30,000/- slip No.97027880 dated 21/09/2022
	The proposed proprietary name / brand name	Pinabax 2.5mg tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban ……2.5mg
	Pharmaceutical form of applied drug	Red, round tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)	Anticoagulant, Cardiovascular, Factor Xa Inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Eliquis Tablets 2.5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute, USFDA Approved.
	For generic drugs (me-too status)	Apixaget 2.5mg Tablet by M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 105247
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved.
	Name and address of API manufacturer.	**API-Apixaban:** CHANGZHOU PHARMACEUTICAL FACTORY. No.518 Laodong East Road, Changzhou, Jiangsu Province 213018, **China.**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity AG-A, AG-G, AG-C, AG-4, AG-II, & , analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: **Apixaban:** Firm has submitted signed and stamped stability data sheets as per zone IV-A in which real time stability data conditions are: Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Eliquis Tablets 2.5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Eliquis Tablets 2.5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and

		acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Linearity, Range, Accuracy, Precision, specificity and/or selectivity, Repeatability, Intermediate precision Robustness, Solution Stability, and LOD & LOQ.

STABILITY STUDY DATA

Manufacturer of API	**API-Apixaban** Changzhou Pharmaceutical Factory.		
API Lot No.	**Apixaban** ZSAP211001		
Description of Pack (Container closure system)	Alu. Alu. Blister strips of 3x10's Tablets packed in a printed unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T018	T025	T026
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	27-04-2022	27-04-2022	27-04-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate Jiangsu Changzhou Pharmaceutical Quality Association valid till 15/09/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software CRF 21 Compliance is not provided, However firm has submitted audit trail reports.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator:

Sr#	Section	Observation	Reply of firm vide dairy No.34064 dated 25-11-2022
01	**1.6.5**	Copy of GMP certificate Jiangsu Changzhou Pharmaceutical Quality Association is	Firm has submitted copy of GMP GMP certificate Jiangsu Changzhou Pharmaceutical Quality Association. Firm also submitted copy

		provided. GMP of Drug Control/Administration of country of origin is required.	of Drug Manufacturing License of API manufacturer issued by provincial Drug and Food Authority of China.
02	**2.3.P.2.1.2**	Firm has mentioned that acceptable limit of Croscarmellose Sodium is 2-5 % w/w , however firm has utilized 9.00 % of Croscarmellose sodium per tablet as disintegrant , which needs clarification/justification.	Firm stated that they decided to use 9 % Croscarmellose Sodium in Apixaban formulation development to improve the dissolution profile of Apixaban. In case of initial formulation, where 5 % Croscarmellose was used, the dissolution results did not meet the required specifications, so we decided to add 9 % to improve the dissolution as the results of which dissolution profile was improved. Croscarmellose sodium is mainly used as a disintegrent in oral pharmaceutical formulations and is generally regarded as essentially nontoxic and nonirritant material. In U.K, Croscarmellose sodium is accepted for use in dietary supplement therefore use of Croscarmellose more than 5 % is safe. WHO has not specified an acceptable daily intake for the related substance carboxymethyl cellulose sodium ,used as food additive ,since the levels necessary to achieve a desired effect were not considered sufficient to be a hazard to health .we have also studied various pharmaceutical formulations papers and found that the use limit may be extended up to 25 %
03	**2.3.P.5.2**	• The testing method specifications/conditions mentioned for Dissolution test does not mentioned 0.05% Sodium lauryl Sulphate to be added along with 6.8 P.H Sodium Phosphate Buffer at 37 C, USP type II apparatus at 75 rpm. 0.05 % SLS is mentioned in release and stability study specification /conditions for conducting dissolution test mentioned in USFDA pharmaceutical review of Innovator product. Clarification is needed. • The chromatographic system used to conduct dissolution assay mentioned UV -242nm whereas for conducting Assay test HPLC is used with detector at UV-280nm. Clarification is needed.	• Firm has stated that they have adopted dissolution of Apixaban Tablet from FDA dissolution data base in which addition of 0.05 % SLS is recommended in P.H 6.8 sodium buffer dissolution media, Same conditions followed throughout the stability testing and same already mentioned in specification and testing method. • The chromatographic system is used to conduct both dissolution & Assay test is 28 nm, same mentioned in chromatographic conditions of dissolution & Assay.
04	**3.2.P.2**	Comparative dissolution profile study is conducted with Eliquis Tablets 5mg by M/s Bristol Myers Squibb Co pharmaceutical Research Institute's , However the dissolution medium used does not mentioned addition of 0.05 % SLS which has been mentioned in Biopharmaceuticals review of USFDA for innovator product tablet Eliquis .Clarification is needed.	Revised Comparative dissolution profile study as per FDA with the addition of 0.05 % SLS is performed and submitted
05	**3.2.P.8.3**	• Documents for the procurement of API with approval from DRAP (in case of import). • COA of Same Batch of API conducted by API manufacturer and subsequently finished product manufacturer. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated	Firm has provided copy of commercial invoice# CYI21376 attested by AD I&E DRAP dated 29-11-2021 for import of 0.1Kg of Apixaban (Batch# ZSAP211001) Not Provided Provided.
Decision: Approved with innovator's specifications.			

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board directed the firm to optimize the formulation for quantity of Crosscarmellose within permissible limits as per Handbook of Pharmaceutical excipients/recommendations of reference regulatoruy authorities, for commercial batches.**

B: REGISTRATION HUMAN (NEW LICENSE) FORM-5

Following Decision of DRAP authority 152th meeting has been communicated by In charge PEC through AD (CEO office) as under:

The Authority, keeping in view the decision of the Appellate Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd, Karachi to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of A.J. Mirza Pharma (Pvt) Ltd, Karachi

1930.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Ajloid Tablet 5mg
	Composition	Each Tablet Contains: Amlodipine Besilate equal to Amlodipine ……5 mg
	Diary No. Date of R & I & fee	Dy. No 34606 dated;30-11-2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Antihypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	2*10's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status	Norvasc Tablet 5mg,Reg#011825, Pfizer Pakistan Ltd., B-2-SITE Karachi. , Karachi
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications. • Chromatographic conditions as provided in Finished testing specifications does not comply USP specifications. • Provision of Dissolution apparatus without Steel paddles or covered with Teflon/inert material to avoid interaction of amlodipine with stainless steel to avoid degradation of amlodipine as required by USP monograph requirement.
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1931.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Ajloid Tablet 10 mg
	Composition	Each Tablet Contains:

		Amlodipine Besilate equal to Amlodipine ……10 mg
	Diary No. Date of R & I & fee	Dy. No 34641 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Antihypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status	Norvasc Tablet 10 mg,Reg#011826, Pfizer Pakistan Ltd., B-2-SITE Karachi. , Karachi
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications. • Chromatographic conditions as provided in Finished testing specifications does not comply USP specifications. • Provision of Dissolution apparatus without Steel paddles or covered with Teflon/inert material to avoid interaction of amlodipine with stainless steel to avoid degradation of amlodipine as required by USP monograph requirement.
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1932.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Diabetin Tablet 100 mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as Phosphate Monohydrate)……100 mg
	Diary No. Date of R & I & fee	Dy. No 34641 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Antidiabetic / Dipeptidyl Peptidase-4 inhibitor
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved , Tal Januvia 100 mg
	Me-too status	Trevia 100mg Tablet, 055437, Getz Pharma, Karachi, , Pakistan, Pakistan
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Disintegration testing specification as NMT 15 minutes which is not as per claimed USP specifications. (05 Minutes) • Assay Limits provided in Finished product testing specifications are 90 % - 110 % of Label Claim, whereas USP Finished product specifications are 95 % - 105 % of Label Claim.
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	

1933.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Diabetin Tablet 50 mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as Phosphate Monohydrate)……50 mg
	Diary No. Date of R & I & fee	Dy. No 34642 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Antidiabetic / Dipeptidyl Peptidase-4 inhibitor
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved , Tal Januvia 50 mg
	Me-too status	Trevia 100mg Tablet, 055436, Getz Pharma, Karachi, , Pakistan, Pakistan
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Disintegration testing specification as NMT 15 minutes which is not as per claimed USP specifications. (05 Minutes) • Assay Limits provided in Finished product testing specifications are 90 % - 110 % of Label Claim, whereas USP Finished product specifications are 95 % - 105 % of Label Claim. • Provided Assay testing method is not as per USP assay testing method (HPLC).
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1934.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Anamid Tablet 1 mg
	Composition	Each Film Coated Tablet Contains: Glimepiride……1 mg
	Diary No. Date of R & I & fee	Dy. No 34627 dated;30/11/2022 Rs.30,000/- dated 18-11-2022 ,
	Pharmacological Group	Hypoglycemic
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	2*10's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved , Tab Amaryl 1 mg.
	Me-too status	Limoride 1mg Tablets, 055682, Brookes Pharmaceuticals, Karachi.
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications.
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1935.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Anamid Tablet 2 mg

	Composition	Each Film Coated Tablet Contains: Glimepiride……2 mg
	Diary No. Date of R & I & fee	Dy. No 34628 dated;30/11/2022 Rs.30,000/- dated 18-11-2022 ,
	Pharmacological Group	Hypoglycemic
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	2*10's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved , Tab Amaryl 2 mg.
	Me-too status	Limoride 2mg Tablets, 055683, Brookes Pharmaceuticals, Karachi.
	GMP status	New License dated 08-11-2022
	Remarks of the Eval6uator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications.
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1936.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Trovin Tablet 20 mg
	Composition	Each Tablet Contains: Atorvastatin Calcium Trihydrate eq to Atorvastatin…… 20mg
	Diary No. Date of R & I & fee	Dy. No 34652 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Lipid Lowering agent
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1*10's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA & MHRA approved. Tab Lipitor 20 mg.
	Me-too status	A-Tin 20mg Tablet,056596, Heal Pharmaceuticals,(Pvt.)Ltd, Peshawar.
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications. • Reference product tablet Lipitor is film coated tablet whereas as applied product label claim on form -5 is uncoated tablet. • Label claim om form-5 mentioned API salt as Atorvastatin calcium monohydrate where as master formulation mentioned API salt as Atorvastatin calcium. • Assay Limits provided in Finished product testing specifications are 90 % - 110 % of Label Claim, whereas USP Finished product specifications are 94.5 % - 105 % of Label Claim. • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications with label claim as under; **Each film coated tablet contains;** **Atorvastatin calcium monohydrate eq to Atorvastatin……20 mg**	

	Firm shall submit revised product testing specification as per USP monograph and revised master formulation ,along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1937.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Trovin Tablet 10 mg
	Composition	Each Tablet Contains: Atorvastatin Calcium Trihydrate eq to Atorvastatin……. 10mg
	Diary No. Date of R & I & fee	Dy. No 34651 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Lipid Lowering agent
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1*10's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA & MHRA approved. Tab Lipitor 10 mg.
	Me-too status	A-Tin 10mg Tablet ,056595, Heal Pharmaceuticals,(Pvt.)Ltd, Peshawar.
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications. • Reference product tablet Lipitor is film coated tablet whereas as applied product label claim on form -5 is uncoated tablet. • Label claim on form-5 mentioned API salt as Atorvastatin calcium monohydrate where as master formulation mentioned API salt as Atorvastatin calcium. • Assay Limits provided in Finished product testing specifications are 90 % - 110 % of Label Claim, whereas USP Finished product specifications are 94.5 % - 105 % of Label Claim. • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications with label claim as under; **Each film coated tablet contains;** **Atorvastatin calcium monohydrate eq to Atorvastatin……10 mg** **Firm shall submit revised product testing specification as per USP monograph and revised master formulation ,along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.**	
1938.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Avaldil Tablet 10/160 mg
	Composition	Each Film coated Tablet Contains: Amlodipine besylate eq. to Amlodipine ……10 mg Valsartan……..…160 mg
	Diary No. Date of R & I & fee	Dy. No 34608 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Antihypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	7*2's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Exforge 10/160 mg tablet, Novartis.

	Me-too status	Exforge 10/160 mg tablet, 047571, NOVARTIS PHARMA Switzerland
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications. • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1939.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Avaldil Tablet 5/160 mg
	Composition	Each Film coated Tablet Contains: Amlodipine besylate eq. to Amlodipine ……5 mg Valsartan…….……160 mg
	Diary No. Date of R & I & fee	Dy. No 34607 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Antihypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	7*2's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Exforge 5/160 mg tablet, Novartis.
	Me-too status	Exforge 5/160 mg tablet, 047570, NOVARTIS PHARMA Switzerland
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications. • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1940.	Name and address of manufacturer/ Applicant	A.J. Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27 ,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Avaldil Tablet 5/80 mg
	Composition	Each Film coated Tablet Contains: Amlodipine besylate eq. to Amlodipine ……5 mg Valsartan……80mg
	Diary No. Date of R & I & fee	Dy. No 34609 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Antihypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	7*2's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA approved, Tab Asbima 5/80 mg
	Me-too status	Exforge 5/80 mg tablet, 047569, NOVARTIS PHARMA Switzerland
	GMP status	New License dated 08-11-2022

	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications. • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1941.	Name and address of manufacturer/ Applicant	A.J.Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Lumart Tablet 20/120 mg
	Composition	Each Tablet Contains: Artemether……...20 mg Lumefantrine……...120 mg
	Diary No. Date of R & I & fee	Dy. No 34610 dated;30/11/2022 Rs.30,000/- dated 17-11-2022 ,
	Pharmacological Group	Antimalarial
	Type of Form	Form - 5
	Finished product Specification	IP
	Pack size & Demanded Price	16's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved, Tablet COARTEM.
	Me-too status	Vizz Tablet, 049384, Shawan Pharmaceuticals, Rawalpindi,
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Firm has applied USP specifications for finished product whereas the monograph is present in International Pharmacopeia.
	Decision: Approved with IP specifications. Firm shall submit revised product testing specification as per IP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1942.	Name and address of manufacturer/ Applicant	A.J.Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Lumart DSTablet 40/240 mg
	Composition	Each Tablet Contains: Artemether……...40 mg Lumefantrine……...240 mg
	Diary No. Date of R & I & fee	Dy. No 34611 dated;30/11/2022 Rs.30,000/- dated 17-11-2022 ,
	Pharmacological Group	Antimalarial
	Type of Form	Form - 5
	Finished product Specification	IP
	Pack size & Demanded Price	16's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Lumeter Tablet 40/240mg, 065263, Advanced Pharmaceuticals, Rawat
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Firm has applied USP specifications for finished product whereas the monograph is present in International Pharmacopeia.
	Decision: Approved with IP specifications. Firm shall submit revised product testing specification as per IP monograph along with preregistration variation fee challan of 7500/=	

	as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1943.	Name and address of manufacturer/ Applicant	A.J.Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Lumart QSTablet 80/480 mg
	Composition	Each Tablet Contains: Artemether……...80 mg Lumefantrine……...480 mg
	Diary No. Date of R & I & fee	Dy. No 34612 dated;30/11/2022 Rs.30,000/- dated 17-11-2022 ,
	Pharmacological Group	Antimalarial
	Type of Form	Form - 5
	Finished product Specification	IP
	Pack size & Demanded Price	16's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Artem DS Plus 80/480 Tablet, 057905, Hilton Pharma,, Karachi, , Pakistan, Pakistan
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Firm has applied USP specifications for finished product whereas the monograph is present in International Pharmacopeia.
	Decision: Approved with IP specifications. Firm shall submit revised product testing specification as per IP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1944.	Name and address of manufacturer/ Applicant	A.J.Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	HC-Valdil Tablet 160/12.5 mg
	Composition	Each Film Coated Tablet Contains: Valsartan ……...160 mg Hydrochlorothiazide……...12.5 mg
	Diary No. Date of R & I & fee	Dy. No 34647 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	2*7's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Co-Valsan 160/12.5 Tablet, 058563, Hilton Pharma(Pvt.)Limited, Pakistan
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1945.	Name and address of manufacturer/ Applicant	A.J.Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	HC-Valdil Tablet 80/12.5 mg

	Composition	Each Film Coated Tablet Contains: Valsartan ……...80 mg Hydrochlorothiazide……..12.5 mg
	Diary No. Date of R & I & fee	Dy. No 34646 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	2*7's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Nuval -D 80/12.5mg Tablet, 066838, Pharm Evo (Pvt) Ltd.,Karachi
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	
1946.	Name and address of manufacturer/ Applicant	A.J.Mirza Pharma (Pvt.) Ltd. Plot No .44,sector 27,Korangi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	HC-Valdil Tablet 160/25 mg
	Composition	Each Film Coated Tablet Contains: Valsartan ……...160 mg Hydrochlorothiazide……..25 mg
	Diary No. Date of R & I & fee	Dy. No 34648 dated;30/11/2022 Rs.30,000/- dated 16-11-2022 ,
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	2*7's, As per current SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status	Nuval -D 160/25mg Tablet, 066840, PharmEvo (Pvt.) Ltd.,Karachi.
	GMP status	New License dated 08-11-2022
	Remarks of the Evaluator	• Finished product specification mentioned Content uniformity testing specification which is not as per claimed USP specifications • Chromatographic conditions as provided in Finished testing specifications for conducting assay test does not comply USP specifications
	Decision: Approved with USP specifications. Firm shall submit revised product testing specification as per USP monograph along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.	

C: REGISTRATION HUMAN (NEW SECTION) FORM 5-F

1947.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories (Pvt) Ltd. 9.5km Sheikhupura Road Lahore
	Name, address of Manufacturing site.	M/s PDH Laboratories (Pvt) Ltd. 9.5km Sheikhupura Road Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28258 dated 05-10-2022
	Details of fee submitted	Rs.30,000/- dated 05-04-2022
	The proposed proprietary name / brand name	**Pd-Care Syrup 60ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Hyoscine Butyl Bromide…5mg
	Pharmaceutical form of applied drug	Clear colorless syrup
	Pharmacotherapeutic Group of (API)	Anti-spasmodic
	Reference to Finished product specifications	Manufacturer Specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not Available
	For generic drugs (me-too status)	SPASLER-P Syrup 5mg/5ml AGP Pharma Reg #016419
	GMP status of the Finished product manufacturer	New GMP license was granted on 27/07/2022. New additional section for oral liquid syrup (General) was approved on June 7,2022.
	Name and address of API manufacturer.	Prism Industries Limited Survey No. 637/23/A1, Khambhat Dhuvaran Road, At Kalamsar, Tal, Khambhat, District. Anand, Gujrat. India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Hyoscine Butyl bromide is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity of related substances , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions:

		Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months Batches: (HBBR-003-03-17, HBBR-002-01-17, HBBR-001-12-16)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Spasler-P syrup 6oml by M/s AGP Pharma Ltd. by performing quality tests (Identification, Assay). Comparative dissolution profile is not applicable
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Prism Industries Limited Survey No. 637/23/A1, Khambhat Dhuvaran Road, At Kalamsar, Tal, Khambhat, District. Anand, Gujrat. India		
API Lot No.	HBBR/02/06/2020		
Description of Pack (Container closure system)	Clear colorless Syrup filled in a ambered glass bottle sealed with aluminium cap packed in a unit carton along with leaflet.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-002	T-003	T-004
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	01/10/2021	02/10/2021	03/10/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. S-GMP/19081515.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.5201/2020/DRAP-AD-CD(I&E) dated 16/04/2020 is submitted wherein the permission to import different APIs including Hyoscine butylbromide for the purpose of test/analysis and stability studies is granted.

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

Remarks of Evaluator:

Sr#	Section	Observation	Reply of the firm vide dairy No.39683 dated 30-11-2022
i.	1.6.5	Provided copy of GMP certificate of API manufacturer is expired.	Valid copy submitted
ii.	1.5.9	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board is not provided.	Firm has provided reference of registration in of Finished product in South Africa and Malaysia. However No evidence of Approval of applied formulation in reference regulatory Authorities as adopted in in 275th meeting is provided.
iii.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendia as well as non-compendial drug substance(s) shall be submitted, which are not provided.	Submitted
iv.	3.2.S.5	Evidence of Compendial Reference standard utilized for development of secondary reference standard is not provided.	The drug substance was tested against potentiometric titration method, in which compendial reference standard is not required.
v.	3.2.P.2.2	Firm has not performed Identification test and viscosity measurement test in COA submitted for demonstration of pharmaceutical equivalence with Syp Spasler of M/s AGP. Clarification is needed.	We have revised the finished product analytical method to include more applications of analytical method and to align the content as per guidelines, hence the revised pharmaceutical equivalence is attached.
vi.	3.2.P.5.1	Firm has not included test for measuring viscosity of finished product in syrup dosage form. Clarification is needed.	Revised Finished product COA as per revised method of analysis are submitted.
vii.	3.2.P.5.2	Firm has not submitted SOP, s for conducting Identification test of Finished product. Clarification is needed	Revised finished product analytical method is submitted.
viii.	3.2.P.8.3	SOP for conducting Analytical method for Assay and Analytical method validation protocol for Assay mentioned testing on HPLC whereas the stability study data demonstrates that Assay testing is conducted through Titration. Clarification in this regard is required. Tests for identification and Viscosity are not included and performed in stability study data , Clarification is needed.	Revised analytical method and analytical method validation protocol report is submitted. Revised stability study protocol and charts are submitted.

Decision: Registration Board has deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

D: Registration (Human) New, Form-5: -

1948.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals (Pvt) LTd.21-Km, Ferozpur Road, Lahore.

		(General Tablet) Section approved
	Brand Name + Dosage Form + Strength	Mino ER Tablet
	Composition	Each Extended Release Tablet Contains: Minocycline Hcl ……..105 mg
	Diary No. Date of R & I & fee	Dy. No 14602 dated 19-04-2018; Rs.20,000/- dated 17-02-2018 , Duplicate Dossier Dy No.30437 dated 27-10-2022.
	Pharmacological Group	Antibiotic
	Type of Form	Form - 5
	Finished product Specification	USP specification
	Pack size & Demanded Price	10's ,
	Approval status of product in Reference Regulatory Authorities	USFDA approved .Tablet Solodyn Extended release tablet containing minocycline Hcl eq to 105 mg of minocycline.
	Me-too status	Tablet Tetra-Derm ER by Valor Pharma (Not verifiable)
	GMP status	GMP certificate issued to M/s Shrooq Pharma based upon evaluation / inspection conducted on 29-10-2021.
	Remarks of the Evaluator	• Firm has applied with label claim as each extended release tablet contains Minocycline Hcl = 105 mg. whereas the USFDA reference product tablet Solodyn is Extended release tablet containing minocycline Hcl eq to 105 mg of minocycline. • Provided Me-too status of Tablet Tetra-Derm ER by Valor Pharma is not verifiable. Valid evidence of me too/generic registered in Pakistan is required.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1949.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals (Pvt) LTd.21-Km, Ferozpur Road, Lahore. (Cream/ointment/lotion/gel) Section approved
	Brand Name + Dosage Form + Strength	Oxy Plus Solution 5 %
	Composition	Each Gram Contains: Minoxidil ……..5 % w/v
	Diary No. Date of R & I & fee	Dy. No 14604 dated 19-04-2018; Rs.20,000/- dated 17-02-2018 , Duplicate Dossier Dy No.30438 dated 27-10-2022.
	Pharmacological Group	Antihypertensive / Vasodilators.
	Type of Form	Form - 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	60 ml
	Approval status of product in Reference Regulatory Authorities	MINOXIDIL EXTRA STRENGTH (FOR MEN). MINOXIDIL EXTRA STRENGTH (FOR WOMEN).USFDA approved as OTC product
	Me-too status	Follinox 5% Solution. Reg. No. 82173
	GMP status	GMP certificate issued to M/s Shrooq Pharma based upon evaluation / inspection conducted on 29-10-2021.
	Remarks of the Evaluator	Firm has mentioned correct master formulation mentioning, each **ml** contains minoxidil…5% w/v. However, label claim mentioned on Form-5 is mentioned as, "each **gram** contains, Minoxidil ….5% w/v.

		Therefore Revised label claim on form -5 as "**Each ml Contains:Minoxidil……50mg (5%)w/v** is required along with pharmacological group as "Other Dermatological".
	Decision: Approved with USP specifications with label claim as under; **Each ml Contains:** **Minoxidil…….50 mg (5% w/v)** **Firm shall submit revised form-5 with above label claim and pharmacological group as "other dermatological" ,along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.**	
1950.	Name and address of manufacturer/ Applicant	M/s Shrooq Pharmaceuticals (Pvt) LTd.21-Km, Ferozpur Road,Lahore. (Cream/ointment/lotion/gel) Section approved.
	Brand Name + Dosage Form + Strength	Oxy Solution 2%
	Composition	Each ml Contains: Minoxidil ……..2 % w/v
	Diary No. Date of R & I & fee	Dy. No 14603 dated 19-04-2018; Rs.20,000/- dated 17-02-2018 , Duplicate Dossier Dy No.30436 dated 27-10-2022.
	Pharmacological Group	Antihypertensive
	Type of Form	Form - 5
	Finished product Specification	Not provided.
	Pack size & Demanded Price	60 ml.
	Approval status of product in Reference Regulatory Authorities	Men's Rogaine 2% topical solution. Women's Rogaine 2% topical solution. USFDA approved as OTC product
	Me-too status	Follinox 2% Solution. Reg. No. 82172
	GMP status	GMP certificate issued to M/s Shrooq Pharma based upon evaluation / inspection conducted on 29-10-2021.
	Remarks of the Evaluator	Revised Pharmacological Group as :Others dermatological".
	Decision: Approved with USP specifications with label claim as under; **Each ml Contains:** **Minoxidil…….20 mg (2% w/v)** **Firm shall submit revised form-5 with above label claim and pharmacological group as "other dermatological" ,along with preregistration variation fee challan of 7500/= as per S.R.O No.7-11/2012-B&A/DRAP dated 07/05/2021 , before issuance of registration letter.**	
1951.	Name and address of manufacturer/ Applicant	Pharmasol (Pvt) Ltd. Plot No. 549, Sundar IndustrialEstate, Raiwind Road, Lahore (Tablet Section)
	Brand Name + Dosage Form + Strength	TRAMAX-SR Tablet 100 mg
	Composition	Each sustained release tablet contains: Tramadol Hydrochloride……100 mg
	Diary No. Date of R & I & fee	Dy.No.12736 dated 06-03-2019; Rs.20,000/- dated 17-02-2018 ,
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form - 5
	Finished product Specification	BP Specification.
	Pack size & Demanded Price	10's,20's,As per SRO
	Approval status of product in Reference Regulatory Authorities	Zydol SR 100 mg prolonged release tablet MHRA approved.
	Me-too status	Volpan SR tab , Reg No. 080368, Rotex Pharma
	GMP status	Firm has submitted copy of GMP certificate No.

		140/2022-DRAP (AD-084433115014) dated 26-08-2022 on the basis of inspection conducted on 22-08-2022.
	Remarks of the Evaluator	
	Decision:Approved.	

E: Registration Applications (Deferred) Form-5: -

1952.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	METABOLASE Injectable Solution
	Composition	Each 100 ml contains: L-Carnitine Hcl(613.3 mg)Equivalent to Carnitine….50 mg D.L Acetylmethionine ……200 mg Cyanocobalamin…….0.2 m A-Tocopherol Acetate(33.0mg) Equivalent to A-Tocopherol……30 mg
	Diary No. Date of R & I & fee	Dy. No 12318 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Amino Acid and vitamins
	Type of Form	Form - 5
	Finished product Specification	Not provided
	Pack size & Demanded Price	100ml, Glass vials.
	Approval status of product in Reference Regulatory Authorities	Not applicable.
	Me-too status	METABOLASE FORTE INJECTABLE SOLUTION, 043109, PRIX PHARMACEUTICA, LAHORE, imported from ITALY
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Form-5 cover letter dully signed by management.

		• Pre-registration variation fee challan.
	Previous Decision of 321th meeting: Deferred for following shortcomings: **1. Master Formulation with Complete Outline of manufacturing method is required.** **2. Complete finished good testing specifications mentioning assay of finished products.** **3. Pack Size, container and closure is not provided.** **4. Form-5 cover letter dully signed by management.** **5. Pre-registration variation fee challan**	
	Reply of Firm: Firm has submitted revised Form-5 along with preregistration fee challan of 30000/= vide slip No 97077652776 dated 07-11-2022. In revised form-5 firm has mentioned revised label claim as under: Each ml contains: L-Carnitine Hcl(61.3mg)Equivalent to L.Carnitine……...50 mg D.L Acetylmethionine ……..……200 mg Cyanocobalamin……0.2 mg Alpha-Tocopherol Acetate(33.0mg) Equivalent to Alpha-Tocopherol……30 mg Revised form-5 also mentioned innovator specifications and pack size of 100 ml in glass vial ,me too status , and revised master formulation along with outline of manufacturing method.	
	Remarks of Evaluator :	
	Decision: Deferred the case for provision of evidence of testing facility along with drug analytical procedure for applied drug product.	
1953.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	COMBIGENT Injection
	Composition	Each 100 ml contains: Gentamycin as sulphate……5 G Tylosin Tartarated……10 G Colistin Sulphate……20 MIU
	Diary No. Date of R & I & fee	Dy. No 12152 dated 06-03-2019; Rs.20,000/- dated 05-03-2019.
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form - 5
	Finished product Specification	Innovator Specification
	Pack size & Demanded Price	50 ml, Glass vial.
	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	C-TYLO G INJECTION,102015, M/S. VETZ PHARMACEUTICALS (PRIVATE) LIMITED., KOTRI SINDH.
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as " In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing , machinery/equipment , material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under maintenance and were not functional at time of inspection": Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin)

		Liquid Injection (hormone) Liquid Injection (Steroid)
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack Size, container and closure is not provided. • Evidence of me-too status of product already registered in Pakistan. • Pre-registration variation fee challan.
	Decision: Deferred for following shortcomings: **1. Master Formulation with Complete Outline of manufacturing method is required.** **2. Complete finished good testing specifications mentioning assay of finished products.** **3. Pack Size, container and closure is not provided.** **4. Evidence of me-too status of product already registered in Pakistan.** **5. Pre-registration variation fee challan.**	
	Reply of Firm : Firm has submitted revised Form-5 along with preregistration fee challan of 7500/= vide slip No 356707771 dated 07-11-2022 .In revised form-5 firm has mentioned innovator specifications and pack size of 50 ml in glass vial ,me too status , and revised master formulation along with outline of manufacturing method.	
	Remarks of Evaluator :	
	Decision : Approved.	
1954.	Name and address of manufacturer/ Applicant	My lab (Pvt) Ltd. Khanqah sharif, Bahawalpur.
	Brand Name + Dosage Form + Strength	METABOLASE FORTE Injectable Solution
	Composition	Each ml Contains: DL-Acetyl methionine 200mg Eq To Cyanocobalamin……0.2mg Carnitine Hcl…61.3mg Eq To Carnitine……50mg A-Tocopherol Acetate……30mg
	Diary No. Date of R & I & fee	Dy. No12319 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.
	Pharmacological Group	Vitamins & Amino acid
	Type of Form	Form - 5
	Finished product Specification	innovator
	Pack size & Demanded Price	50 ml glass vial
	Approval status of product in Reference Regulatory Authorities	Not Applicable
	Me-too status	METABOLASE FORTE INJECTABLE SOLUTION, 043109, PRIX PHARMACEUTICA, LAHORE, imported from ITALY
	GMP status	Panel GMP inspection was conducted on 24-02-2021 and 25-02-2021 and concluded as“ In view of above inspection proceedings and facilities verified such as company profile, building ,production, in process controls, quality control testing, machinery/equipment, material management , air handling, water treatment system , personnel and documentation etc. the firm M/s Mylab (pvt) Ltd. Khanqah sharif Bahawalpur , was found to be operating at a satisfactory level of GMP compliance for the following sections only, oral Liquid (General)II and Aerosol section were under

		maintenance and were not functional at time of inspection" Liquid Injection Section (General) Oral Powder Premix Section (General) Oral Liquid (General)(I) Liquid Injection (penicillin) Dry Powder Injection (penicillin) Oral Powder (penicillin) Liquid Injection (hormone) Liquid Injection (Steroid)
	Remarks of the Evaluator	• Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • The applied composition does not resemble to me to provided, i-e Metabolase Forte Injection. Submit revised label claim composition as per applied me to.
	Decision: Deferred for following shortcomings: • Master Formulation with Complete Outline of manufacturing method is required. • Complete finished good testing specifications mentioning assay of finished products. • Pack size, container and closure are not provided. • Undertaking at ending of Form-5 • The applied composition does not resemble to me to provided, i-e Metabolase Forte Injection. Submit revised label claim composition as per applied me to	
	Reply of Firm: Firm has submitted revised Form-5 along with preregistration fee challan of 30000/= vide slip No 94376926835 dated 16-11-2022. In revised form-5 firm has mentioned revised label claim as under: Each ml contains: L-Carnitine Hcl (61.3mg)Equivalent to L.Carnitine……...50 mg D.L Acetylmethionine ……..……200 mg Cyanocobalamin……0.2 mg Alpha-Tocopherol Acetate(33.0mg) Equivalent to Alpha-Tocopherol……30 mg Revised form-5 also mentioned innovator specifications and pack size of 50 ml in glass vial ,me too status , and revised master formulation along with outline of manufacturing method.	
	Decision: Deferred the case for provision of evidence of testing facility along with drug analytical procedure for applied drug product.	

Agenda of Evaluator PEC-XVII.

Case No. 1: REGISTRATION APPLICATIONS (RE-GRANT OF NEW LICENSE OF M/S A.J MIRZA) FOR LOCAL MANUFACTURING OF (HUMAN) DRUGS ON FORM-5.

Decision: (152nd Meeting of Authority)

The Authority, keeping in view the decision of the Appellate Board, exercising its power under Rule 26 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 amended via SRO 713(1)/2018 dated 8th June, 2018, decided to grant one time exemption to M/s A.J Mirza Pharma (Pvt) Ltd, Karachi to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F for those drugs whose registrations were cancelled, due to cancellation of Drug

Manufacturing License on account of non-submission of renewal application within the specified time, or those registration applications which were approved by the Registration Board at the time of cancellation of DML of A.J. Mirza Pharma (Pvt) Ltd, Karachi.		
1955	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ajlol 50mg Tablet
	Composition	Each tablet contains: Atenolol…..…50mg
	Diary No. Date of R & I & fee	Form-5, Dy.No 34650 dated 30-11-2022, Fee Rs.30,000/- vide online deposit slip No. 7045477479 dated 16-11-2022
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5.
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per current SRO / Pack of 2×10's blister
	Approval status of product in Reference Regulatory Authorities	TENORMIN®, AstraZeneca pharmaceuticals (US FDA approved)
	Me-too status	Lotonol 50mg tablet of M/s Lotus Pharmaceuticals Islamabad. Registration No. 090167
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • The product is available both as un-coated and film-coated tablet. • Tab. Ajlol 50mg, Registration No. 101031 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved.	
1956	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ajlol 100mg Tablet
	Composition	Each tablet contains: Atenolol…..…100mg
	Diary No. Date of R & I & fee	Form-5, Dy.No 34649 dated 30-11-2022, Fee Rs.30,000/- vide online deposit slip No. 72248148031 dated 16-11-2022
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5.
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per current SRO / Pack of 2×10's blister
	Approval status of product in Reference Regulatory Authorities	(US FDA approved)
	Me-too status	Atelomir 100mg Tablet of M/s Fahmir Pharma (Pvt) Ltd, Sheikhupura. Registration No. 101549
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • The product is available both as un-coated and film-coated tablet. • Tab. Ajlol 100mg, Registration No. 101030 was previously registered in the name of M/s A.J.M Pharma, Karachi.

	Decision: Approved.	
1957	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJSTATIN 10mg Tablet
	Composition	Each film-coated tablet contains: Rosuvastatin Calcium Eq. to Rosuvastatin…10mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34640 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.95691236012 dated 16-11-2022.
	Pharmacological Group	Lipid lowering agent
	Type of Form	Form-5.
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×10's blister
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)
	Me-too status	Novitin 10mg Tablet, 3S Pharmaceuticals, Lahore. Registration No. 100542
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator(PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. AJSTATIN 10mg, Registration No. 103054 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with USP specifications. **• Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1958	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ajstatin 20mg Tablet
	Composition	Each film-coated tablet contains: Rosuvastatin Calcium Eq. to Rosuvastatin…20mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34639 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.0450136169 dated 17-11-2022.
	Pharmacological Group	Lipid lowering agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×10's blister
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)
	Me-too status	Novitin 20mg Tablet, 3S Pharmaceuticals, Lahore. Registration No. 100543.
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise finished drug product specifications as per official monograph (USP).

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. AJSTATIN 20mg, Registration No. 103054 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with USP specifications. **• Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1959	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LEVTITAM 250mg Tablet
	Composition	Each tablet contains: Levetiracetam……...250mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34631 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.26806325 dated 17-11-2022.
	Pharmacological Group	Antiepileptic agent
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 3×10's blister
	Approval status of product in Reference Regulatory Authorities	KEPPRA® 250 mg, 500 mg, 750 mg, and 1000 mg film-coated, scored tablets (USFDA approved)
	Me-too status	Levepil 250mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087690
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise label claim as per reference product as: Each film-coated tablet contains: Levetiracetam……250mg • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. LEVTITAM 250mg, Registration No. 100357 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with revised label claim as: **Each film-coated tablet contains:** **Levetiracetam……250mg** **• Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1960	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Levtitam 500mg Tablet
	Composition	Each tablet contains: Levetiracetam…….500mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34630 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.50454647860 dated 17-11-2022.
	Pharmacological Group	Antiepileptic agent
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×10's blister

	Approval status of product in Reference Regulatory Authorities	KEPPRA® 250 mg, 500 mg, 750 mg, and 1000 mg film-coated, scored tablets (USFDA approved)
	Me-too status	Levepil 250mg tablet of M/s Evolution Pharmaceuticals, Islamabad. Registration No. 087690
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise label claim as per reference product as: Each film-coated tablet contains: Levetiracetam……500mg • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. LEVTITAM 500mg, Registration No. 100356 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with revised label claim as: **Each film-coated tablet contains:** **Levetiracetam……500mg** **• Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1961	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	VALDIL 80mg Tablet
	Composition	Each film-coated tablet contains: Valsartan…….80mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34645 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.770899773 dated 16-11-2022.
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 2×7's blister
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)
	Me-too status	Cibavan-80 film-coated tablet of M/s Ciba Pharmaceuticals, Karachi. Registration No. 102906
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise pharmacological group as "Angiotensin II receptor blockers (ARBs), plain". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. VALDIL 80mg, Registration No. 103062 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved. Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1962	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.

	Brand Name + Dosage Form + Strength	VALDIL 160mg Tablet
	Composition	Each film-coated tablet contains: Valsartan…...…160mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34644 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.8249788228 dated 16-11-2022.
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 2×7's blister
	Approval status of product in Reference Regulatory Authorities	(USFDA approved)
	Me-too status	Cibavan-160 film-coated tablet of M/s Ciba Pharmaceuticals, Karachi. Registration No. 102907
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise pharmacological group as "Angiotensin II receptor blockers (ARBs), plain". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. VALDIL 160mg, Registration No. 103061 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved. Firm shall submit the fee of Rs. 7,500 for variation in registration application i.e., correction/change of pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	
1963	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	DOMIRONE 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Domperidone Maleate Eq. to Domperidone…10mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34623 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.89509788028 dated 16-11-2022.
	Pharmacological Group	Dopamine antagonist
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 5×10's
	Approval status of product in Reference Regulatory Authorities	MHRA approved both as un-coated & film-coated tablet. Motilium is film-coated tablet
	Me-too status	Doperdone Tablet 10mg of M/s Hiranis Pharmaceuticals, Karachi. Registration No. 103163
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise finished drug product specifications as per official monograph (BP). • Revise pharmacological group as "Propulsives". • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.

		• Tab. DOMIRONE 10mg, Registration No. 100359 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with BP specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1964	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJBISOL 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate…5mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34615 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.855834407608 dated 16-11-2022.
	Pharmacological Group	(Cardio-selective) Adrenoceptor blocking agent
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 2×10's
	Approval status of product in Reference Regulatory Authorities	Zebeta® 5mg, 10mg film-coated tablet (USFDA approved)
	Me-too status	Brupal 5mg Tablet of M/s Biomark Pharmaceuticals, Lahore. Registration No. 103342
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Tab. AJBISOL 5mg, Registration No. 103041 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved.	
1965	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJBISOL 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate……10mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34616 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.1278876414 dated 16-11-2022.
	Pharmacological Group	(Cardio-selective) Adrenoceptor blocking agent
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 2×10's
	Approval status of product in Reference Regulatory Authorities	Zebeta® 5mg, 10mg film-coated tablet (USFDA approved)
	Me-too status	Brupal 10mg Tablet of M/s Biomark Pharmaceuticals, Lahore. Registration No. 103343.
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Tab. AJBISOL 10mg, Registration No. 103042 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved.	

1966	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	ATHICIN 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin……250mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34613 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.55799465 dated 16-11-2022.
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×6's
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Hicwic Tablet 250mgof M/s Winthrox Laboratories, Karachi. Registration No. 101171.
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Tab. ATHICIN 250mg, Registration No. 103043 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved.	
1967	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	ATHICIN 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin……500mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34614 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.19490209588 dated 16-11-2022.
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×6's
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Azomax 500mg tablet of M/s Novartis Pharma, Karachi. Registration No. 045415
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Tab. ATHICIN 500mg, Registration No. 103044 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved.	
1968	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJCIP 250mg Tablet
	Composition	Each Tablet Contains: Ciprofloxacin HCl Eq. to Ciprofloxacin…250mg

	Diary No. Date of R & I & fee	Form-5 Dy.No 34619 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.09780666033 dated 16-11-2022.
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×10's
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Cunnocip 250mg Tablet of M/s Cunningham Pharmaceuticals Lahore. Registration No. 103319
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise label claim as per reference product as: Each film-coated tablet Contains: Ciprofloxacin HCl Eq. to Ciprofloxacin…250mg • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. AJCIP 250mg, Registration No. 100355 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with revised label claim as: **Each film-coated tablet Contains:** **Ciprofloxacin HCl Eq. to Ciprofloxacin…250mg** • **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1969	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJCIP 500mg Tablet
	Composition	Each tablet contains: Ciprofloxacin HCl Eq. to Ciprofloxacin…500mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34618 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.00364327646 dated 16-11-2022.
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×10's
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Cunnocip 250mg Tablet of M/s Cunningham Pharmaceuticals Lahore. Registration No. 103319
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise label claim as per reference product as: Each film-coated tablet Contains: Ciprofloxacin HCl Eq. to Ciprofloxacin…500mg

		• For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. AJCIP 500mg, Registration No. 100354 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with revised label claim as: **Each film-coated tablet Contains:** **Ciprofloxacin HCl Eq. to Ciprofloxacin…500mg** • **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition (correction/change of formulation from un-coated tablet to film coated tablet), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1970	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJDICLOF-Na 50mg Tablet
	Composition	Each Delayed Release Tablet Contains: Diclofenac Sodium…50mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34620 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.4272176273 dated 16-11-2022.
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per current SRO / Pack of 2×10's
	Approval status of product in Reference Regulatory Authorities	VOLTAREN® 25mg, 50mg, 75mg Delayed release tablet (USFDA approved) **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	Me-too status	Techfen 50mg Tablet of M/s Curatech Pharma (Pvt) Ltd.,Multan Road Lahore. Registration No. 101667
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. AJDICLOF-Na 50mg, Registration No. 103066 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with USP specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1971	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJDICLOF-SR 100mg Tablet
	Composition	Each Sustained Release Tablet Contains: Diclofenac Sodium……...100mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34621 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.33393602007 dated 16-11-2022.
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications

	Pack size & Demanded Price	As per current SRO / Pack of 1×10's
	Approval status of product in Reference Regulatory Authorities	VOLTAREN-XR (diclofenac sodium film coated extended release) tablets 100mg, (USFDA Approved) Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	Techfen SR 100mg Tablet of M/s Curatech Pharma (Pvt) Ltd.,Multan Road Lahore. Registration No. 101666.
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise label claim as per reference product as: Each Sustained Release film-coated tablet contains: Diclofenac Sodium……...100mg • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. AJDICLOF-SR 100mg, Registration No. 103065 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with USP specifications and revised label claim as: Each Sustained Release film-coated tablet contains: Diclofenac Sodium……...100mg • **Firm shall submit fee of Rs. 7,500 for correction/pre-approval change in composition and product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1972	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	MOXICTA 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Moxifloxacin HCl Eq. to Moxifloxacin…400mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34633 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.0410987403 dated 16-11-2022.
	Pharmacological Group	antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×5's
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Oxef 400mg Tablet of M/s Parmedic laboratories, Lahore. Registration No. 100852
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise pharmacological group as "Fluoroquinolones". • Revise finished drug product specifications as per official monograph (USP). • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021.

		• Tab. MOXICTA 400mg, Registration No. 103188 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with USP specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1973	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	BONTAN 62.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Bosentan…….62.5mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34617 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.69289690 dated 16-11-2022.
	Pharmacological Group	Antagonist at Endothelin receptor types
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per current SRO / Pack of 1×14's
	Approval status of product in Reference Regulatory Authorities	TRACLEER® 62.5 & 125mg film-coated tablet (USFDA approved)
	Me-too status	Bistona Tablet 62.5mgof M/s Sigma pharma, Karachi. Registration No. 098521
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise label claim as per reference product as: Each Film Coated Tablet Contains: Bosentan (As monohydrate) …….62.5mg • Revise pharmacological group as "Antihypertensives for pulmonary arterial hypertension". • The product is non-pharmacopoeial. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. BONTAN 62.5mg, Registration No. 103067 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with innovator's specifications and revised label claim as: **Each Film Coated Tablet Contains:** **Bosentan (As monohydrate) …….62.5mg** • **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1974	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	HEPCRIB 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Ribavirin……..…400mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34653 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.1237514865 dated 17-11-2022.
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications

	Pack size & Demanded Price	As per current SRO / Packs of 10's
	Approval status of product in Reference Regulatory Authorities	COPEGUS® 200mg & 400mg film-coated tablet (USFDA approved) **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	Me-too status	Rivab 400mg Tablet of M/s Nabiqasim Industries, Karachi. Registration No. 095985
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Tablet Section (General) mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise finished drug product specifications as per official monograph. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • Tab. HEPCRIB 400mg, Registration No. 103063 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with USP specifications. **• Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1975	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	LEVTITAM 500mg/5ml Syrup
	Composition	Each 5ml Contains: Levetiracetam…….500mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34632 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.0470594824 dated 17-11-2022.
	Pharmacological Group	Anti-epileptic agent
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per current SRO / 30ml
	Approval status of product in Reference Regulatory Authorities	KEPPRA® 100mg/ml solution (USFDA approved)
	Me-too status	Xeticam Oral Solution 100mg/ml of M/s Herbion Pakistan, Islamabad. Registration No. 102862
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Liquid Syrup (General) Section mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Syp. LEVTITAM 500mg/5ml, Registration No. 100358 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved.	
1976	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	DOMIRONE 5mg/5ml Suspension
	Composition	Each 5ml Contains: Domperidone…….5mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34622 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.59804746978 dated 17-11-2022.
	Pharmacological Group	Anti-emetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications

	Pack size & Demanded Price	As per current SRO / 120ml
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Domilium 5mg/5ml suspension of M/s Jinnah Pharmaceuticals, Multan. Registration No. 099610
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Liquid Syrup (General) Section mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise pharmacological group as "Propulsives". • The product is non-pharmacopoeial. • BP monographs for both base and maleate forms of API are available. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • DOMIRONE 5mg/5ml Suspension, Registration No. 103064 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with innovator's specifications. • **Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1977	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	AJ-IPS Syrup
	Composition	Each 5ml Contains: Iron Protien Succinylate…….266.67mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34629 dated 30-11-2022, Fee Rs.30,000/- dated 16-11-2022 vide online deposit slip No.10399491 dated 16-11-2022.
	Pharmacological Group	Iron deficiency anaemia
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per current SRO / 60ml
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	HG Syrup 800mg/15ml of M/s Maxitech pharma, Karachi. Registration No. 101147
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (PEC-XVII)	• Liquid Syrup (General) Section mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Revise label claim as: Each 15ml contains: Iron protein succinylate 800mg eq. to elemental Iron….40mg • The product is non-pharmacopoeial. • For above revision, submit applicable fee as per notifications 7-11/2012-B&A/DRAP dated 07-05-2021 & 13-07-2021. • AJ-IPS Syrup (Iron protein succinylate: 266.67/5ml), Registration No. 103045 was previously registered in the name of M/s A.J.M Pharma, Karachi.
	Decision: Approved with innovator's specifications and revised label claim as: **Each 15ml contains:** **Iron protein succinylate 800mg eq. to elemental Iron…….40mg**	

	• **Firm shall submit the fee of Rs. 30,000 for correction/pre-approval change in composition (correction/change of salt form of the drug substance), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**	
1978	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	ETAPHYLLINE 125mg/5ml Syrup
	Composition	Each 5ml Contains: Acefylline Piperazine……..…125mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34655 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.188915020616 dated 17-11-2022.
	Pharmacological Group	Xanthine drugs
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per current SRO / 60ml, 120ml
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Brophyl syrup of M/s Stanley pharmaceuticals, Peshawar. Registration No. 069788
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator(PEC-XVII)	• Liquid Syrup (General) Section mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation). • Provide evidence of approval of applied formulation in reference regulatory authorities which were declared/adopted by the Drug Registration Board in its 275th meeting. • Firm has claimed USP specifications. However, USP monograph could not be confirmed. • The product is non-pharmacopoeial. • ETAPHYLLINE 125mg/5ml Syrup, Registration No. 006553 was previously registered (transfer of registration) in the name of M/s A.J.M Pharma, Karachi.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted/declared by Registration Board in its 275th meeting.	
1979	Name and address of manufacturer/ Applicant	M/s A.J Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector 27, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	ETAPHYLLINE Cough Syrup
	Composition	Each 5ml Contains: Acefylline Piperazine…….45mg Diphenhydramine HCl……8mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 34654 dated 30-11-2022, Fee Rs.30,000/- dated 17-11-2022 vide online deposit slip No.839926088 dated 17-11-2022.
	Pharmacological Group	Xanthine drugs, antihistamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	As per current SRO / 60ml, 100ml
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Acelyf Syrup of M/s Hicon pharmaceuticals, Peshawar. Registration No. 077431
	GMP status	DML re-granted w.e.f 08-11-2022.
	Remarks of the Evaluator (EC-XVII)	• Liquid Syrup (General) Section mentioned in panel inspection report dated 22-08-2022 for the Re-grant of Drug Manufacturing License (By way of Formulation).

		• Provide evidence of approval of applied formulation in reference regulatory authorities which were declared/adopted by the Drug Registration Board in its 275th meeting. • In the online fee deposit slip/challan the firm has mentioned following composition: Acefylline Piperazine…….45mg/5ml Diphenhydramine HCl……8mg/5ml Ammonium Chloride…….13mg/5ml • The product is non-pharmacopoeial. • ETAPHYLLINE Cough Syrup, Registration No. 010915 was previously registered (transfer of registration) in the name of M/s A.J.M Pharma, Karachi.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted/declared by Registration Board in its 275th meeting. • **Clarification from firm is required since in the online fee deposit slip/challan, the following composition, which is different than the applied, is given.** **Acefylline Piperazine…….45mg/5ml** **Diphenhydramine HCl……8mg/5ml** **Ammonium Chloride…….13mg/5ml**	

Case No. 2: WITHDRAWAL OF REGISTRATION APPLICATIONS FOR LOCAL MANUFACTURING OF HUMAN DRUGS ON FORM-5F BY M/S FORTUNE PHARMACEUTICALS, PLOT NO. K/201, S.I.T.E, SUPER HIGHWAY, PHASE-II, KARACHI.

M/s Fortune Pharma Private Limited. (New DML)

CLB in its 278th meeting held on 10th and 11th December 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following five (05) sections to M/s Fortune Pharma Private Limited

	Tablet (General)		Liquid Ampoule (General)
	Liquid Syrup (General)		Liquid Vial (General)
	Capsule (General)		Tablet (Psychotropic)
	Ointment (General) Section		Capsule (Psychotropic)
	Sachet (General)		Liquid Ampoule (Psychotropic)

It is submitted that following cases of the firm were evaluated. However, the firm M/s Fortune Pharmaceuticals, Plot no. K/201, S.I.T.E, Super Highway, Phase-II, Karachi vide letter no. Nil dated 23-11-2022, received vide R & I diary No.34113 dated 25-11-2022, informed with reference to P E & R Division, letter No.F.15-1/2022 PEC dated 18-11-2022 wherein panel has been constituted for verification of Authentication of Product Development and Stability data for below mentioned products, stated that they have lost relevant data for mentioned applications due to computer and software problem, therefore they withdrawn the applications voluntarily for below Drug Products.

Sr.#	**Product Name & Composition**	**Sr.No.**	**Product Name & Composition**
01.	Vomita 4mg tablet Each film-coated tablet contains:	04.	Fexomark 60mg tablet Each film-coated tablet contains:

	Ondansetron HCl……4mg 02. Vomita 8mg tablet Each film-coated tablet contains: Ondansetron HCl……8mg 03. F-Ezole 20mg capsule Esomeperazole Magnisium Trihydrate E.q to to Esomeperazole 20mg	Fexofenadine HCl….60mg 05. Fexomark 120mg tablet Each film-coated tablet contains: Fexofenadine HCl….120mg 06. Fexomark 180mg tablet Each film-coated tablet contains: Fexofenadine HCl….180mg
1980.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.
	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No 27133 dated 26-09-2022.
	Details of fee submitted	Rs.30,000/- vide challan No. 71571260 dated 20-07-2022.
	The proposed proprietary name / brand name	VOMITA 4mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ondansetron hydrochloride……..…4mg
	Pharmaceutical form of applied drug	White color round shaped film-coated tablet, packed in Alu-Alu blisters (1×10's) and further packed in printed unit cartons along with a patient information leaflet.
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 × 10's
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	ZOFRAN® 4 mg film-coated tablet (ondansetron hydrochloride dihydrate equivalent to 4 mg of ondansetron) by Novartis pharmaceuticals, Co. (USFDA approved)
	For generic drugs (me-too status)	OND4 4mg film-coated tablet (Ondansetron hydrochloride dihydrate eq to ondansetron: 4mg), Registration No. 102512 of M/s

		Innvotek Pharmaceuticals, Islamabad.
	GMP status of the Finished product manufacturer	New DML (DML No. 000924 granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Evidence of section approval.	Tablet (General) Section approval granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 06 & 09 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (AOND-17002, AOND-17003 & AOND-17004)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its composition, formulation development, pharmaceutical equivalence, comparative dissolution profile, manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zofran 4mg tablet of M/s GSK,

		Pakistan by performing quality tests such as Identification, Assay, Dissolution and Uniformity of dosage unit. Comparative dissolution profile (CDP) has been performed against the same brand that is Zofran 4mg tablet of M/s GSK, Pakistan in Acid media (pH 1.0-1.2), Acetate Buffer pH 4.5 & Phosphate Buffer (pH 6.8). Discrepancy in data observed. Details given below in remarks column.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.		
API Lot No.	AOND-21001		
Description of Pack (Container closure system)	1 × 10's in Alu-Alu blisters, packed in a printed carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-01	T-01
Batch Size	15,000 tablets	15,000 tablets	15,000 tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-01-2022	01-01-2022	01-01-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
Administrative Portion		
7.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted M/s Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru, Karnataka, India.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Incomplete submission as raw data sheets, summary data sheets, content uniformity data and dissolution data not provided.
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks OF Evaluator: (PEC-XVII)

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Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	• The strength/label claim provided is not in accordance with the innovators product that is: Each film-coated tablet contains: Ondansetron (as HCl dihydrate) …….4mg	
2.	1.6.5 (b)	• No evidence of approval of manufacturing facility of API by concerned regulatory body submitted.	
3.	2.3.S.4.4	• The firm has provided HPLC method verification summary instead of Batch analysis data.	
4.	2.3.P.2.2.1 (a)	• In the formulation development, both film-coating and enteric coating processes mentioned, while the applied formulation is film-coated tablet.	
5.	3.2.S.4.1	• Specifications for drug substance provided by the drug product manufacturer has two different values for residue on ignition test. Clarification shall be submitted.	
6.	3.2.S.4.2	• Analytical procedure (signed) for the drug substance by the drug product manufacturer shall be submitted.	
13.	3.2.S.7.3	• Incomplete long term stability studies summary data sheets (only for 6 & 9 months) for the drug substance have been submitted by the firm.	
14.	3.2.P.1 (b)	• The qualitative composition is not in line with innovator's formulation, since the pre-gelatinized starch is not mentioned in applicant formulation. Provide scientific justification.	
15.	3.2.P.1 (b)	• The API quantity given without considering salt factor of the API. As evident from the trial batches BMR attached at 2.3.R.1, the quantity of API has been dispensed/mentioned without salt factor calculation.	

16.	3.2.P.2.2.1	• (ii) In pharmaceutical equivalence specifications comparison table, the applied product (Vomita 4mg tablet) is mentioned of some other firm and not of the applicant itself.	
17.	3.2.P.2.2.1 (iii)	• In comparative dissolution profile table, the time points mentioned as 5, 10, 15, 20, 25 & 30 minutes, however, during calculation, the time points given in calculation of similarity factor, the last time point mentioned as 45 minutes.	
18.	3.2.P.2.2.1 (iii)	• The buffer for pH 4.5 has been mentioned as Phosphate buffer instead of Acetate buffer.	
19.	3.2.P.2.2.1 (iii)	• The comparative dissolution profile for Acetate buffer, the % dissolution values for sample No. 5 to 12 at all-time points have significantly decreased for reference product. The similarity factor (f2) turns out to be 33. Provide scientific justifications for the particular dissolution profile.	
20.	3.2.P.2.2.1 (iii)	• The comparative dissolution data submitted for both strengths of Vomita tablet 4mg & Vomita tablet 8mg is same in all three buffers. All the dissolutions values at all-time points for all the samples have same values. Please clarify and scientifically justify.	
21.	3.2.P.2.6	• The excipients mentioned includes colloidal anhydrous silica, however, the same excipient has not been mentioned in other sections of the dossier such as composition, batch formula, formulation development etc.	
22.	3.2.P.3.3	• Granulation process has been mentioned in manufacturing process, however, the product is being manufactured through direct compression, clarification is required.	
23.	3.2.P.3.5	• In the process validation SOP, under list of equipment, rotary granulator, FBD, oscillating granulator are mentioned. However, the product to be manufactured through direct compression process.	
24.	3.2.P.3.5	• In the process validation SOP, under packing, the firm has mentioned packing of capsules (2×7's), instead of applied product.	
25.	3.2.P.5.2	• The assay method of FPP is not in accordance with that given in official	

		monograph (USP) of Ondansetron tablets. For sample solution preparation, the firm has mentioned 10 tablets, while as per official monograph, 20 tablets to be taken, from which portion of powder, equivalent to 50mg of Ondansetron, to be transferred. The applied strength is 4mg ondansetron (as HCl dihydrate). • Moreover, as per official monograph standard solution concentration is 0.05mg/ml of Ondansetron (free base) in diluent (Acetonitrile & Buffer, 1:1) from USP Ondansetron HCl RS. While the firm has provided as 0.2mg/ml of USP Ondansetron HCl RS in mobile phase. • The method also varies with respect to sample stock solution preparation and column specifications.	
26.	3.2.P.5.2	• The dissolution method varies from the USP official monograph of Ondansetron HCl tablet in terms of standard solution preparation and result analysis formula. Clarification is required.	
27.	3.2.P.5.2	• The dissolution limit mentioned NLT 80% of Ondansetron HCl in 30 minutes, while in official monograph, the limit mentioned as NLT 80% (Q) of Ondansetron HCl in 15 minutes. (Test 1)	
28.	3.2.P.5.2	• The dosage form uniformity test provided on the basis of weight variation (USP General monograph Uniformity of Dosage unit <905>), however as per label claim/strength (4mg/tablet), the content uniformity test is recommended.	
29.	3.2.P.5.2	• In the specifications table, the identification test of the FPP given as of HPLC. However, in analytical procedure, the identification tests mentioned the test for chloride.	
30.	3.2.P.8.3	• Provide raw data sheets, summary data sheets, audit trial reports and digital data logger record for temperature & humidity monitoring of stability chambers (both real and accelerated) in support of stability studies performed of the trial batches.	
31.	3.2.P.8.3	• The wavelength mentioned in chromatogram/HPLC reports submitted is 328nm, however, as per analytical procedures submitted and	

		official monograph of the product, the wave length for assay determination is 216nm.	
32.	3.2.P.8.3	• Provide raw data sheets for dissolution determination of trial batches during stability studies performed.	
33.	3.2.P.8.3	• The firm has mentioned content uniformity test in CoA of trial batches (at all-time points). Provide raw data sheets and chromatograms/HPLC reports for the content uniformity tests.	
34.	3.2.P.8.3	• The time intervals among the chromatograms/HPLC reports of standard and samples analysis, mostly vary from 1-3minutes. While the runtime for each analysis is 15 minutes, with retention time of peaks for all standards and samples as 3.770-3.774 (approx. 3.77). Clarification and scientific justification is required in this regard, as to how such intervals among chromatograms possible, with aforementioned peak retention times and run time of the analysis performed.	
35.	3.2.R.1.1	• The BMR of trial batches (T-01, T-02 & T-03) submitted are blank BMRs, having no details of actual execution of production/manufacturing of the trial batches, such as personnel signatures, in-process checks, reconciliation record, time intervals for different manufacturing steps, quantities dispensed etc.	
36.		Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
37.		Documents for the procurement of API with approval from DRAP (in case of import)	
38.		Compliance record of HPLC software 21CFR & audit trail reports on product testing.	
39.		Record of digital data logger for temperature and humidity monitoring of both stability chambers.	
Decision: Registration Board noted the request of the firm for withdrawal of the instant application and declared it as rejected.			
1981.		Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.
		Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals, Plot No. K/201, S.I.T.E, Super Highway, Phase-II, Karachi.

	Status of the applicant	☒ Manufacturer. ☐ Importer. ☐ Is involved in none of the above (contract giver).
	Status of application	☐ New Drug Product (NDP). ☒ Generic Drug Product (GDP).
	Intended use of pharmaceutical product	☐ Domestic sale. ☐ Export sale. ☒ Domestic and Export sales.
	Dy. No. and date of submission	Dy. No 27134 dated 26-09-2022.
	Details of fee submitted	Rs.30,000/- vide challan No. 75896857 dated 20-07-2022.
	The proposed proprietary name / brand name	VOMITA 8mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ondansetron hydrochloride……..…8mg
	Pharmaceutical form of applied drug	White color round shaped film-coated tablet, packed in Alu-Alu blisters (1×10's) and further packed in printed unit cartons along with a patient information leaflet.
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 × 10's
	Proposed unit price	As per policy.
	The status in reference regulatory authorities	ZOFRAN® 8 mg film-coated tablet (ondansetron hydrochloride dihydrate equivalent to 8 mg of ondansetron) by Novartis pharmaceuticals, Co. (USFDA approved)
	For generic drugs (me-too status)	OND8 8mg film-coated tablet (Ondansetron hydrochloride dihydrate eq to ondansetron: 8mg), Registration No. 102513 of M/s Innvotek Pharmaceuticals, Islamabad.
	GMP status of the Finished product manufacturer	New DML (DML No. 000924 granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Evidence of section approval.	Tablet (General) Section approval granted vide Licensing Division letter No.F.2-3/2016-Lic dated 22-02-2021.
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.

	Module-II (Quality Overall Summary)	Firm has submitted Quality Overall Summary: Product Dossier details as per WHO QOS-PD template.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Incomplete stability studies summary data sheets of drug substance submitted: Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 06 & 09 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (AOND-17002, AOND-17003 & AOND-17004)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its composition, formulation development, pharmaceutical equivalence, comparative dissolution profile, manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Zofran 8mg tablet of M/s GSK, Pakistan by performing quality tests such as Identification, Assay, Dissolution and Uniformity of dosage unit. Comparative dissolution profile (CDP) has been performed against the same brand that is Zofran 8mg tablet of M/s GSK, Pakistan in Acid media (pH 1.0-1.2), Acetate Buffer pH 4.5 & Phosphate Buffer (pH 6.8). Discrepancy in data

		observed. Details given below in remarks column.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Anugraha Chemicals, No. D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate Doddaballapur, Bengaluru-561203, India.		
API Lot No.	AOND-21001		
Description of Pack (Container closure system)	1 × 10's in Alu-Alu blisters, packed in a printed carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-01	T-01
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-01-2022	01-01-2022	01-01-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not submitted M/s Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSSIDC Industrial Estate, Doddaballapur, Bengaluru, Karnataka, India.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted Quantity received 1kg as mentioned in CoA of API by drug product manufacturer. Date of received 12-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Incomplete submission as raw data sheets, summary data sheets, content uniformity data and dissolution data not provided.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks OF Evaluator: (PEC-XVII)

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	• The strength/label claim provided is not in accordance with the innovators product that is: Each film-coated tablet contains: Ondansetron (as HCl dihydrate) …….4mg	
2.	1.6.5 (b)	• No evidence of approval of manufacturing facility of API by concerned regulatory body submitted.	
3.	2.3.S.4.4	• The firm has provided HPLC method verification summary instead of Batch analysis data.	
4.	2.3.P.2.2.1 (a)	• In the formulation development, both film-coating and enteric coating processes mentioned, while the applied formulation is film-coated tablet.	
5.	3.2.S.4.1	• Specifications for drug substance provided by the drug product manufacturer has two different values for residue on ignition test. Clarification shall be submitted.	
6.	3.2.S.4.2	• Analytical procedure (signed) for the drug substance by the drug product manufacturer shall be submitted.	
7.	3.2.S.7.3	• Incomplete long term stability studies summary data sheets (only for 6 & 9 months) for the drug substance have been submitted by the firm.	
8.	3.2.P.1 (b)	• The qualitative composition is not in line with innovator's formulation, since the pre-gelatinized starch is not mentioned in applicant formulation. Provide scientific justification.	
9.	3.2.P.1 (b)	• The API quantity given without considering salt factor of the API. As evident from the trial batches BMR attached at 2.3.R.1, the quantity of API has been dispensed/mentioned without salt factor calculation.	
10.	3.2.P.2.2.1	• (ii) In pharmaceutical equivalence specifications comparison table, the applied product (Vomita 4mg tablet) is mentioned of some other firm and not of the applicant itself.	
11.	3.2.P.2.2.1 (iii)	• In comparative dissolution profile table, the time points mentioned as 5, 10, 15, 20, 25 & 30 minutes, however, during calculation, the time points	

		given in calculation of similarity factor, the last time point mentioned as 45 minutes.
12.	3.2.P.2.2.1 (iii)	• The buffer for pH 4.5 has been mentioned as Phosphate buffer instead of Acetate buffer.
13.	3.2.P.2.2.1 (iii)	• The comparative dissolution profile for Acetate buffer, the % dissolution values for sample No. 5 to 12 at all-time points have significantly decreased for reference product. The similarity factor (f2) turns out to be 33. Provide scientific justifications for the particular dissolution profile.
14.	3.2.P.2.2.1 (iii)	• The comparative dissolution data submitted for both strengths of Vomita tablet 4mg & Vomita tablet 8mg is same in all three buffers. All the dissolutions values at all-time points for all the samples have same values. Please clarify and scientifically justify.
15.	3.2.P.2.6	• The excipients mentioned includes colloidal anhydrous silica, however, the same excipient has not been mentioned in other sections of the dossier such as composition, batch formula, formulation development etc.
16.	3.2.P.3.3	• Granulation process has been mentioned in manufacturing process, however, the product is being manufactured through direct compression, clarification is required.
17.	3.2.P.3.5	• In the process validation SOP, under list of equipment, rotary granulator, FBD, oscillating granulator are mentioned. However, the product to be manufactured through direct compression process.
18.	3.2.P.3.5	• In the process validation SOP, under packing, the firm has mentioned packing of capsules (2×7's), instead of applied product.
19.	3.2.P.5.2	• The assay method of FPP is not in accordance with that given in official monograph (USP) of Ondansetron tablets. For sample solution preparation, the firm has mentioned 10 tablets, while as per official monograph, 20 tablets to be taken, from which portion of powder, equivalent to 50mg of Ondansetron, to be transferred. The applied strength is 4mg ondansetron (as HCl dihydrate).

20.	3.2.P.5.2	• The dissolution method varies from the USP official monograph of Ondansetron HCl tablet in terms of standard solution preparation and result analysis formula. Clarification is required.	
21.	3.2.P.5.2	• The dissolution limit mentioned NLT 80% of Ondansetron HCl in 30 minutes, while in official monograph, the limit mentioned as NLT 80% (Q) of Ondansetron HCl in 15 minutes (Test 1).	
22.	3.2.P.5.2	• The dosage form uniformity test provided on the basis of weight variation (USP General monograph Uniformity of Dosage unit <905>), however as per label claim/strength (4mg/tablet), the content uniformity test is recommended.	
23.	3.2.P.5.2	• In the specifications table, the identification test of the FPP given as of HPLC. However, in analytical procedure, the identification tests mentioned the test for chloride.	
24.	3.2.P.8.3	• Provide raw data sheets, summary data sheets, audit trial reports and digital data logger record for temperature & humidity monitoring of stability chambers (both real and accelerated) in support of stability studies performed of the trial batches.	
25.	3.2.P.8.3	• The wavelength mentioned in chromatogram/HPLC reports submitted is 328nm, however, as per analytical procedures submitted and official monograph of the product, the wave length for assay determination is 216nm.	
26.	3.2.P.8.3	• Provide raw data sheets for dissolution determination of trial batches during stability studies performed.	
27.	3.2.P.8.3	• The firm has mentioned content uniformity test in CoA of trial batches (at all-time points). Provide raw data sheets and chromatograms/HPLC reports for the content uniformity tests.	
28.	3.2.P.8.3	• The time intervals among the chromatograms/HPLC reports of standard and samples analysis, mostly vary from 1-3minutes. While the runtime for each analysis is 15 minutes, with retention time of peaks for all standards and samples as 3.770-3.774 (approx. 3.77). Clarification and	

		scientific justification is required in this regard, as to how such intervals among chromatograms possible, with aforementioned peak retention times and run time of the analysis performed.
29.	3.2.R.1.1	• The BMR of trial batches (T-01, T-02 & T-03) submitted are blank BMRs, having no details of actual execution of production/manufacturing of the trial batches, such as personnel signatures, in-process checks, reconciliation record, time intervals for different manufacturing steps, quantities dispensed etc.
30.		Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
31.		Documents for the procurement of API with approval from DRAP (in case of import)
32.		Compliance record of HPLC software 21CFR & audit trail reports on product testing.
33.		Record of digital data logger for temperature and humidity monitoring of both stability chambers.

Decision: Registration Board noted the request of the firm for withdrawal of the instant application and declared it as rejected.

1982.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals Private Limited Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Limited Plot K/201 S.I.T.E. (SHW) Phase II, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12390 dated 21/05/2022
	Details of fee submitted	PKR 30,000/-: dated 27/04/2022
	The proposed proprietary name / brand name	F -EZOLE 20mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeperazole Magnisium Trihydrate E.q to to Esomeperazole 20mg
	Pharmaceutical form of applied drug	A dark blue cap with blue body size "3" hard Gelatin filled capsule having white pallets.

	Pharmacotherapeutic Group of (API)	Drugs for acid-related disorders, Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	1×14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM 20mg Capsule USFDA. Esomeprazole 20mg Gastro – resistant capsule MHRA
	For generic drugs (me-too status)	ACIREG CAPSUL 20 mg BARRETT HODGSON PAKISTAN (PVT) LTD
	GMP status of the Finished product manufacturer	New license granted on 21/02/2021 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,Karachi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Esomeprazole Mg is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ESO-EC – 22.5-001-19, ESO-EC – 22.5-002-19, ESO-EC – 22.5-003-19)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is ACIREG CAPSULE 20 mg Capsule by BARRETT HODGSON PAKISTAN (PVT) LTD. performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is ACIREG CAPSULE 20 mg by BARRETT HODGSON PAKISTAN (PVT) LTD.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA			
Manufacturer of API	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,		
API Lot No.	21GT1 2003		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FE-001	FE-002	FE-003
Batch Size	1400 capsule	1400 capsule	1400 capsule
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	02-03-2020	02-03-2020	02-03-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document. Because of new DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022**
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase from M/s. Saakh Pharma, Karachi

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	HPLC software 21CFR not Installed
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:[PEC-XVI]

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Provide COA of primary / secondary reference standard including source and lot number used for testing of drug substance.
- Clarification is required regarding the assay results of stability data of drug substance, either the quantity is of anhydrous esomeprazole magnesium or the labelled amount of esomeprazole.
- Justify how 88.888mg esomeprazole magnesium 22.5% enteric coated pellets are equivalent to 20mg esomeprazole as stated in section 3.2. P.1.
- Calculations of comparative dissolution profile is not in accordance with guidelines approved in 293rd meeting of Registration Board with reference to following points:
  - For f2 calculations a minimum of three time points (excluding point zero) must be used; **mentioned the time point which were considered for the calculation of f2 value.**
  - A maximum of one time-point should be considered after 85% dissolution of the innovator / reference product has been reached; **but as per the submitted documents you have used all time point until 30minutes, which are all below 85%. Clarify how you have calculated the f2 without considering the time point after 85% drug release.**
- Provide dissolution profile in pH 4.5 medium of drug product to comply the decision of 293rd meeting of Registration Board, which states that "The results of comparative dissolution profile conducted in three BCS media across the physiological pH range along with calculation of similarity factor f2 should be submitted and discussed.
- Justify how the results of comparative dissolution profile in all the physiologic medium yields f2 factor value 80.
- Justify how you have claimed USP specification when the given analytical method is not in accordance with USP monograph of "***Esomeprazole Magnesium Delayed-Release Capsules".***
- Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- According to the USP monograph of "***Esomeprazole Magnesium Delayed-Release Capsules",*** result of identification test should be represent as the ratio of the retention times of the esomeprazole peak in the Standard solution and the Sample solution and the acceptance criteria is 0.98-1.02, while in the stability data of drug product, you have mentioned the specification of identification test as "the retention time of the major peak in the chromatogram of sample preparation correspond to that in the chromatogram of the standard peak. Justify, how the specification of drug complies the USP specification.
- Clarify, why you have not mentioned the results of dissolution test in acidic medium in the stability data of drug product. Further, the specification of dissolution test did not mention the time limit in which NLT 75% (Q) should be achieved.

- Following variations have been observed between the assay method given in section 3.2. P.5.2 and the raw data sheet of stability data attached in section 3.2. P.8.
  - According to assay method given in section 3.2.P.5.2 the column temperature should be ambient while the raw data sheets revealed that column temperature was maintained 40°C.
  - Dimensions of column mentioned in section 3.2. p.5.2 was different from dimensions mentioned on raw data sheets of section 3.2. P.8.
  - Composition of mobile phase also differ in both aforesaid sections.
- Justify the disparate weight of sample and standard used for preparation of final conc. of solution mentioned on raw data sheets of stability study with reference to the assay method specified in section 3.2. P.5.2.
- Raw data sheets of dissolution testing have not been attached in section 3.2. P.8., provide raw data sheet to analyse the result of dissolution of all six units.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board noted the request of the firm for withdrawal of the instant application and declared it as rejected.

1983.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharma Private Limited Head Office Suit # 731, 7th Floor Mashriq Centre, Opp National Stadium Road Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22074 dated 03-08-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 27292455344
	The proposed proprietary name / brand name	Fexomark 60mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine Hydrochloride 60mg
	Pharmaceutical form of applied drug	White color round shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	1 ×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telfast 60mg film-coated tablets.by Sanofi Consumer Healthcare TGA approved.
	For generic drugs (me-too status)	Fexet 60mg film coated Tablet by Getz Pharma .
	GMP status of the Finished product manufacturer	New DML letter issued dated; 22-02-2021
	Name and address of API manufacturer.	**VPL Chemicals Pvt. Ltd**

		Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala Taluk, Bengaluru Rural-562111, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Fexofenadine Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and impurities and water content have been performed, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(FE III 1503013, FE III 1503014, FE III 1503015)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Telfast 60mg** by **Sanofi-Aventis** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Telfast 60mg** by **Sanofi-Aventis** in Acid media (pH 1.0-1.2) and pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API		VPL Chemicals Pvt. Ltd Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala Taluk, Bengaluru Rural-562111, India
API Lot No.		FEX2103012
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (1×10's)

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	10-10-2021	10-10-2021	10-10-2021
No. of Batches	03		

Administrative Portion

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

Remarks OF Evaluator:[PEC-IV]

S.No	Section	Shortcomings Communicated Reply
1.	1.6.5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
3.	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.
4.	3.2.P.2.2.1	Pharmaceutical equivalence and CDP of Fexomark 60mg and Fexomark 120mg have same data.
5.	3.2.P.5.1	Justify your acceptance criteria for dissolution test as NLT 60% of the labeled amount of Fexofenadine HCl is dissolved in 10 min; NLT 80% of the labeled amount of Fexofenadine HCl is dissolved in 30 min while USP has specified as NLT 60% (Q) of the labeled amount of Fexofenadine HCl dissolved in 10 min; NLT 80% (Q) of the labeled amount of Fexofenadine HCl dissolved in 30 min.
6.	3.2.P.5.4	• Justify dissolution results in the submitted batch analysis since results are not complying USP monograph. • For Batch #T-02 and T-03, Date of manufacture, 05-2021 and date of tests are 10-05-2021 while in summary sheets of stability studies are 10-2021. • Average weight in specifications is 125mg ±5.0 % while in certificate of analysis, average weight is 250mg ±5.0 %
7.	3.2.P.5.6	• Average weight in specifications is 125mg ±5.0 % while in justification of specifications, average weight is 250mg ±7.5%

8.	3.2.P.8	• Documents for the procurement of API with approval from DRAP (in case of import). • Average weight in stability studies summary sheets 280mg ±7.5 % and COA's 180mg ±7.5 % while in specifications 125mg ±5.0 % • Chromatograms for Assay for Fexomark 60mg, Fexomark 120mg, Fexomark 120mg are same. • Dissolution chromatograms are not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: Registration Board noted the request of the firm for withdrawal of the instant application and declared it as rejected.

1984.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharma Private Limited Head Office Suit # 731, 7th Floor Mashriq Centre, Opp National Stadium Road Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22075 dated 03-08-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 84554320025
	The proposed proprietary name / brand name	Fexomark 120mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine Hydrochloride 120mg
	Pharmaceutical form of applied drug	White color round shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	1 ×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telfast 120 mg film-coated tablets.by Aventis Pharma Limited UK (MHRA Approved)
	For generic drugs (me-too status)	Fexet 120 mg film coated Tablet by Getz Pharma Reg. No. 029435
	GMP status of the Finished product manufacturer	New DML letter issued dated; 22-02-2021
	Name and address of API manufacturer.	**VPL Chemicals Pvt. Ltd**

		Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala Taluk, Bengaluru Rural-562111, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Fexofenadine Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and impurities and water content have been performed, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(FE III 1503013, FE III 1503014, FE III 1503015)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Telfast 120 mg** by **Sanofi-Aventis** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Telfast 120 mg** by **Sanofi-Aventis** in Acid media (pH 1.0-1.2) and pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	VPL Chemicals Pvt. Ltd Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala Taluk, Bengaluru Rural-562111, India
API Lot No.	FEX2103012

Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	10-10-2021	10-10-2021	10-10-2021
No. of Batches	03		

Administrative Portion

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

Remarks OF Evaluator: PEC-IV

S.No	Section	Shortcomings Communicated Reply
9.	1.6.5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
10	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
11	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.
12	3.2.P.2.2.1	Pharmaceutical equivalence and CDP of Fexomark 60mg and Fexomark 120mg have same data.
13	3.2.P.5.1	Justify your acceptance criteria for dissolution test as NLT 60% of the labeled amount of Fexofenadine HCl is dissolved in 10 min; NLT 80% of the labeled amount of Fexofenadine HCl is dissolved in 30 min while USP has specified as NLT 60% (Q) of the labeled amount of Fexofenadine HCl dissolved in 10 min; NLT 80% (Q) of the labeled amount of Fexofenadine HCl dissolved in 30 min.
14	3.2.P.5.4	• Justify dissolution results in the submitted batch analysis since results are not complying USP monograph. • For Batch #T-01, T-02 and T-03, Date of manufacture, 05-2021 and date of tests are 10-05-2021 while in summary sheets of stability studies are 10-2021.

15	3.2.P.8	• Documents for the procurement of API with approval from DRAP (in case of import). • Average weight in stability studies summary sheets 280mg ±7.5% and COA's 250mg ±7.5%. • Chromatograms for Assay for Fexomark 60mg, Fexomark 120mg, Fexomark 120mg are same. • Dissolution chromatograms are not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: Registration Board noted the request of the frim for withdrawal of the instant application and declared it as rejected.

1985.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharma Private Limited Head Office Suit # 731, 7th Floor Mashriq Centre, Opp National Stadium Road Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharma Private Limited Plot # K/201,S.I.T.E (SHW) Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22076 dated 03-08-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 6956083068
	The proposed proprietary name / brand name	Fexomark 180mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Fexofenadine Hydrochloride 180mg
	Pharmaceutical form of applied drug	White color round shaped film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-histamine
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	1 ×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Telfast 180 mg film-coated tablets.by Aventis Pharma Limited UK (MHRA Approved)
	For generic drugs (me-too status)	Fexet 180 mg film coated Tablet by Getz Pharma Reg. No. 029436
	GMP status of the Finished product manufacturer	New DML letter issued dated; 22-02-2021
	Name and address of API manufacturer.	**VPL Chemicals Pvt. Ltd**

		Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala Taluk, Bengaluru Rural-562111, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Fexofenadine Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Identification, Assay and impurities and water content have been performed, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(FE III 1503013, FE III 1503014, FE III 1503015)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Telfast 180 mg** by **Sanofi-Aventis** by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is **Telfast 180 mg** by **Sanofi-Aventis** in Acid media (pH 1.0-1.2) and pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	VPL Chemicals Pvt. Ltd Plot # 64, 1st Phase, Sompura Industrial area Dobbespet, Neelamangala Taluk, Bengaluru Rural-562111, India		
API Lot No.	FEX2103012		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	10-10-2021	10-10-2021	10-10-2021
No. of Batches	03		

Administrative Portion

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

Remarks OF Evaluator: PEC-IV

S.No	Section	Shortcomings Communicated Reply
16	1.6.5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin
17	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3
18	3.2.S.5	COA of primary / secondary reference standard including source and lot number shall be provided.
19	3.2.P.2.2.1	Pharmaceutical equivalence and CDP of Fexomark 60mg and Fexomark 120mg have same data.
20	3.2.P.5.1	Justify your acceptance criteria for dissolution test as NLT 60% of the labeled amount of Fexofenadine HCl is dissolved in 10 min; NLT 80% of the labeled amount of Fexofenadine HCl is dissolved in 30 min while USP has specified as NLT 60% (Q) of the labeled amount of Fexofenadine HCl dissolved in 10 min; NLT 80% (Q) of the labeled amount of Fexofenadine HCl dissolved in 30 min.

21	3.2.P.5.4	• Justify dissolution results in the submitted batch analysis since results are not complying USP monograph. • For Batch #T-02 and T-03, Date of manufacture, 05-2021 and date of tests are 10-05-2021 while in summary sheets of stability studies are 10-2021.
22	3.2.P.8	• Documents for the procurement of API with approval from DRAP (in case of import). • Chromatograms for Assay for Fexomark 60mg, Fexomark 120mg, Fexomark 120mg are same. • Dissolution chromatograms are not submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Decision: Registration Board noted the request of the frim for withdrawal of the instant application and declared it as rejected.

Agenda of Evaluator PEC-XVIII.

1986.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WALLACE PHARMA EVOLUTIONS, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site.	M/s WALLACE PHARMA EVOLUTIONS, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31476 dated 02.11.2022
	Details of fee submitted	PKR 30,000/-: dated 27.10.2022
	The proposed proprietary name / brand name	Ropen (Meropenem) 500mg injection.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Meropenem as Trihydrate ……. 500mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's Vial
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Merrem Injection (USFDA)
	For generic drugs (me-too status)	Ropen Injection of Macter International Karachi
	GMP status of the Finished product manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. The summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted the accelerated and real time stability data for three batches.
	Stability studies	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including BET and Sterility) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III (Drug Product):	Firm has submitted the accelerated and real time stability data for three batches.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Merem 500mg injection of Global Pharmaceuticals Islamabad
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.** Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.		
API Batch No.	682104002		
Description of Pack (Container closure system)	1 Vial packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	M-01	M-02	M-03
Batch Size	500 Injection	500 Injection	500 Injection
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	17-04-2022	17-04-2022	17-04-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML granted vide license No. 000951 dated 23.12.2021
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP issued by CFDA vide No. HE20180065 dated 17.08.2018 which is valid till 1608.2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has taken loan of 5Kg of API from M/s Ipram International Rawat Islamabad for product development purpose. The firm has also submitted the DRAP attested documents confirming the import of 10kg of API imported vide invoice No. 2021ZN-0017 dated 24.02.2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The submitted data includes chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	21CFR Compliance record is not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm submitted record of data logger for temperature and humidity monitoring of stability chambers

Remarks:

Sr.#	Observations	Firm's response
1.	Documents regarding the local procurement of 5Kg of API or DRAP attested invoice in case of import.	The firm has taken loan of 5Kg of API from M/s Ipram International Rawat Islamabad for product development purpose. The firm has also submitted the DRAP attested documents confirming the import of 10kg of API imported vide invoice No. 2021ZN-0017 dated 24.02.2021.
2.	3.2.S.4.1 The specifications proposed by the API manufacturer indicates assay ≥ 78%, however USP monograph states 90-120%, this needs clarification.	The firm clarified limits for assay showed in the form of potency. Firm has also submitted revised specifications according to USP
3.	3.2. S.4.4Justification of doing batch analysis of API with the Innovator product and the batch analysis indicates the 80% Meropenem in your and Innovator product. This needs justification.	Written mistakenly innovator instead of API manufacturer, and has submitted revised batch analysis report.
4.	3.2.S.7.3 the stability data does not indicate tests for sodium content, this needs to be clarified.	Firm has submitted revised stability studies data from drug substance manufacturer where in test of "Sodium content" has been reported. Firm has also submitted commercial invoice dated 08-12-2021 for the "Atomic absorption spectrophotometer".
5.	3.2.5.P.1 The identification test (B) of USP monograph needs to be submitted with respective UV spectrums by using diode array detector.	Firm has referred to the HPLC Assay test for identification test as per USP monograph.
6	You have proposed specifications of sodium content by Atomic Absorption Spectroscopy as per USP Monograph, hence latest inspection report needs to be submitted confirming the availability of the Atomic Absorption. Spectrophotometer including its IQ/OQ/PQ. Further spectra's needs to be submitted for the trial batches confirming the quantification of sodium content	Firm has submitted spectra's indicating the quantification of sodium content.
6.	3.2.P.5.2 Analytical procedures for sterility and BET needs to be submitted.	Submitted.

7.	3.2.P.4 The batch analysis report does not reflect the tests for the sodium content, however same is proposed in finished product specifications.	Firm has submitted batch analysis reports with results of sodium content test.
8.	3.2.P.6 Certificate of analysis of reference standard needs to be submitted.	Certificate of analysis of reference standard is submitted
9.	3.2. P.8.3 The stability data does not reflect the tests for the sterility and BET and sodium content, this needs justification.	Firm has submitted revised stability data sheets reflecting the tests for the sterility and BET and sodium content, this needs justification.
10.	3.2. R.1.1. The BMR of liquid injection is submitted instead the applied product. BMR of the applied product needs to be submitted.	Revised BMR of applied product has been submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**
- **Firm shall submit Pharmaceutical equivalence studies against the innovator product along with IQ, OQ & PQ reports of "Atomic Absorption Spectrophotometer" before issuance of registration letter.**
- **Registration Board further deciced that registration letter will be issued upon verification of drug substance loan leter by "M/s Ipram International Rawat Islamabad".**

1987.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WALLACE PHARMA EVOLUTIONS, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site.	M/s WALLACE PHARMA EVOLUTIONS, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31477 dated 02.11.2022
	Details of fee submitted	PKR 30,000/-: dated 27.10.2022
	The proposed proprietary name / brand name	**Ropen 1g Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Meropenem as Trihydrate ……. 1g
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Carbapenem
	Reference to Finished product specifications	USP
	Proposed Pack size	1's Vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Merrem Injection (USFDA)
	For generic drugs (me-too status)	Ropen Injection of Macter International Karachi
	GMP status of the Finished product manufacturer	New DML granted vide license No. 000951 dated 23.12.2021

	Name and address of API manufacturer.	CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd. No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. The summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted the accelerated and real time stability data for three batches.
	Stability studies	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including BET and Sterility) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Module-III (Drug Product):	Firm has submitted the accelerated and real time stability data for three batches.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Merem 500mg injection of Global Pharmaceuticals Islamabad
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	**CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co., Ltd.** Address: No. 88 Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province, China.		
API Batch No.	682104002		
Description of Pack (Container closure system)	1 Vial packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	M-04	M-05	M-06
Batch Size	500 Injection	500 Injection	500 Injection
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	17-04-2022	17-04-2022	17-04-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML granted vide license No. 000951 dated 23.12.2021

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP issued by CFDA vide No. HE20180065 dated 17.08.2018 which is valid till 1608.2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has taken loan of 5Kg of API from M/s Ipram International Rawat Islamabad for product development purpose. The firm has also submitted the DRAP attested documents confirming the import of 10kg of API imported vide invoice No. 2021ZN-0017 dated 24.02.2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The submitted data includes chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	21CFR Compliance record is not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm submitted record of data logger for temperature and humidity monitoring of stability chambers

Remarks:

Sr.#	Observations	Firm's response
1.	Documents regarding the local procurement of 5Kg of API or DRAP attested invoice in case of import.	The firm has taken loan of 5Kg of API from M/s Ipram International Rawat Islamabad for product development purpose. The firm has also submitted the DRAP attested documents confirming the import of 10kg of API imported vide invoice No. 2021ZN-0017 dated 24.02.2021.
2.	3.2.S.4.1 The specifications proposed by the API manufacturer indicates assay ≥ 78%, however USP monograph states 90-120%, this needs clarification.	The firm clarified limits for assay showed in the form of potency. Firm has also submitted revised specifications according to USP
3.	3.2. S.4.4Justification of doing batch analysis of API with the Innovator product and the batch analysis indicates the 80% Meropenem in your and Innovator product. This needs justification.	Written mistakenly innovator instead of API manufacturer, and has submitted revised batch analysis report.
4.	3.2.S.7.3 the stability data does not indicate tests for sodium content, this needs to be clarified.	Firm has submitted revised stability studies data from drug substance manufacturer where in test of "Sodium content" has been reported.
5.	3.2.5.P.1 The identification test (B) of USP monograph needs to be submitted with respective UV spectrums by using diode array detector.	Firm has referred to the HPLC Assay test for identification test as per USP monograph.
6	You have proposed specifications of sodium content by Atomic Absorption Spectroscopy as per USP Monograph, hence latest inspection report needs to be submitted confirming the availability of the Atomic Absorption. Spectrophotometer including its IQ/OQ/PQ. Further spectra's needs to be submitted for the trial batches confirming the quantification of sodium content	Firm has submitted spectra's indicating the quantification of sodium content. Firm has also submitted commercial invoice dated 08-12-2021 for the "Atomic absorption spectrophotometer".
6.	3.2.P.5.2 Analytical procedures for sterility and BET needs to be submitted.	Submitted.
7.	3.2.P.4 The batch analysis report does not reflect the tests for the sodium content, however same is proposed in finished product specifications.	Firm has submitted batch analysis reports with results of sodium content test.
8.	3.2.P.6 Certificate of analysis of reference standard needs to be submitted.	Certificate of analysis of reference standard is submitted
9.	3.2. P.8.3 The stability data does not reflect the tests for the sterility and BET and sodium content, this needs justification.	Firm has submitted revised stability data sheets reflecting the tests for the sterility and BET and sodium content, this needs justification.

	10.	3.2. R.1.1. The BMR of liquid injection is submitted instead the applied product. BMR of the applied product needs to be submitted.	Revised BMR of applied product has been submitted.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall state the quantity, in mg, of sodium (Na) in a given dosage of Meropenem, on the label claim, as recommended by the USP monograph of "Meropenem for injection".**
- **Firm shall submit Pharmaceutical equivalence studies against the innovator product along with IQ, OQ & PQ reports of "Atomic Absorption Spectrophotometer" before issuance of registration letter.**
- **Registration Board further deciced that registration letter will be issued upon verification of drug substance loan leter by "M/s Ipram International Rawat Islamabad".**

1988.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WALLACE PHARMA EVOLUTIONS, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site.	M/s WALLACE PHARMA EVOLUTIONS, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32467 dated 11.11.2022
	Details of fee submitted	Rs. 30000/- dated 07.11.2022
	The proposed proprietary name / brand name	Nemcil (Imipenem and Cilastatin) 250mg/250mg injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Imipenem and Cilastatin ……. 250mg/250mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Imipenem and Cilastatin is a new beta-lactam antibiotic belonging to the Carbapenem class.
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	GMP status of the Finished product manufacturer	New DML granted vide license No. 000951 dated 23.12.2021
	Name and address of API manufacturer.	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph exists in USP. The firm has submitted details regarding nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted the accelerated and real time stability data for three batches.
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including BET and Sterility) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Cilapen 250/250mg injection of** Bosch Pharmaceuticals, Karachi, Pakistan. by performing quality tests.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA			
Manufacturer of API	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.		
API Batch No.	DCIMCNF063		
Description of Pack (Container closure system)	1 Vial packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	150 Injection	150 Injection	150 Injection
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	25-04-2022	25-04-2022	25-04-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML granted vide license No. 000951 dated 23.12.2021
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted the copy of GMP certificate of API manufacturer issued by the Office of Drug Controller Food and Drugs Administration of Madya Pardesh India

3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted that they have acquired 5Kg of API from M/s Ipram Pharmaceuticals International Rawat Islamabad. The firm has submitted copy of COA vide batch No. DCIMCNF06 Mfg date 10.2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm does not submitted CFR compliance documents.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Manual record maintained

Remarks:

Sr.#	Observations	Firm's response
1.	Copy of DRAP attested invoice for import of API by Ipram Pharmaceuticals International Rawat Islamabad for the batch No. DCIMCNF063.	The firm has submitted that they have acquired 5Kg of API from M/s Ipram Pharmaceuticals International Rawat Islamabad. The firm has submitted copy of COA vide batch No. DCIMCNF06 Mfg date 10.2021 along with permission letter from DRAP I&E Islamabad in name of M/s IPRAM.
2.	Page 2 of the CoA of the API manufacturer is not legible, hence legible copy needs to be submitted. Justification for performing analysis of API with the innovator brand.	Submitted. Written mistakenly innovator instead of API manufacturer, and has submitted revised batch analysis report.
3.	Justification for performing identification by IR as it is not the requirement of USP monograph and same is not performed by the API manufacturer.	IR identification was written mistakenly in our API COA, revised/corrected COA has now been submitted.
4.	USP monograph states the assay limits for both Cilastatin and Imipenem 90-105%, however your limits are 41.67% to 53.24% as per CoA submitted by you. The requires clarification.	The firm clarified limits for assay showed in the form of potency. Firm has also submitted revised specifications according to USP
5.	3.2.S.4.1The specifications/ assay limits proposed by the API manufacturer in respect of assay are different from the USP monograph, this needs justification.	API manufacturer limits show in the form of separate potencies of Imipenem and Cilastatin but USP monograph shows limits in combine Imipenem/Cilastatin.
6.	3.2.S.4.2The analytical procedures by the API manufacturer needs to be submitted.	Submitted.
7.	3.2.S.5 Certificate of analysis of reference standards for both Imipenem and Cilastatin needs to be submitted	Submitted
8.	3.2.S.7 Legible copies of stability sheets needs to be submitted with conclusion on shelf life and storage conditions.	Submitted.
9.	3.2. P.1 The quantity of API per unit needs to be submitted as per label claim with calculations because the submitted details are not satisfactory.	Frim has submitted revised calculations have been submitted based upon potency.
10.	3.2.P.2.2The Pharmaceutical equivalence study does not reflect the tests for sterility and BET, this needs clarification.	Revised PE study data has been submitted indicating performance of Sterility and BET test.
11.	3.2. P.3 Justification required for manufacturing of three different batches while using the sterile API in one cycle of production. The batch formula need to be	150 vials were written mistakenly. The quantity of API used to manufacture product for 500 vials for each trial.

	clarified with the quantity of API used to manufacture 150 vials on one batch.	
12.	3.2. P.5.2 Analytical procedures for sterility and BET needs to be submitted.	Submitted.
13.	3.2. P.6 CoA's of reference standard	Submitted.
14.	3.2.P.7 Details of container closure system.	Submitted.
15.	3.2.P.8 Clarification required for not performing Sterility and BET during stability.	Revised stability data sheets including results of sterility test & BET test has been submitted.

Decision: Approved.

- **M/s Wallace Pharma Evolutions, shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit Pharmaceutical equivalence studies against the innovator product before issuance of registration letter.**
- **Registration Board further deciced that registration letter will be issued upon verification of drug substance loan leter by "M/s Ipram International Rawat Islamabad".**

1989.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wallace Pharma Evolutions, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.**
	Name, address of Manufacturing site.	M/s Wallace Pharma Evolutions, Kalalwala stop, 20-KM, Lahore Jaranwala Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32468 dated 11.11.2022
	Details of fee submitted	Rs. 30000/- dated 07.11.2022
	The proposed proprietary name / brand name	Nemcil 500mg/500mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem and Cilastatin ……. 500mg/500mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Imipenem and Cilastatin is a new beta-lactam antibiotic belonging to the Carbapenem class.
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection USFDA
	For generic drugs (me-too status)	Tienam Injection of OBS Pakistan Karachi
	GMP status of the Finished product manufacturer	New DML granted vide license No. 000951 dated 23.12.2021

	Name and address of API manufacturer.	M/s Sun Pharmaceutical Industries Limited, Industrial Area No. 3, A.B. Road, Dewas 455 001 (MP), India.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph exists in USP. The firm has submitted details regarding nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Firm has submitted the accelerated and real time stability data for three batches.
	Module-III (Drug Product):	The firm has submitted details of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including BET and Sterility) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Cilapen 500/500 injection of** Bosch Pharmaceuticals, Karachi, Pakistan. By performing quality tests.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, 2187pecificity.

STABILITY STUDY DATA

Manufacturer of API	M/S Sun Pharmaceutical Industries Limited, Industrial Area No. 3 A.B. Road, Dewas 455 001 (MP), India.		
API Batch No.	DCIMCNF063		
Description of Pack (Container closure system)	1 Vial packed in unit carton (1×1's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-04	T-05	T-06
Batch Size	150 Vials	150 vials	150 vials
Manufacturing Date	04-2022	04-2022	04-2022

Date of Initiation	23.04.2022	23.04.2022	23.04.2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	New DML granted vide license No. 000951 dated 23.12.2021
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted the copy of GMP certificate of API manufacturer issued by the Office of Drug Controller Food and Drugs Administration of Madya Pardesh India
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted that they have acquired 5Kg of API from M/s Ipram Pharmaceuticals International Rawat Islamabad. The firm has submitted copy of COA vide batch No. DCIMCNF06 Mfg date 10.2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm does not submitted CFR compliance documents.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Manual record maintained

Remarks:

Sr.#	Observations	Firm's response
1.	Copy of DRAP attested invoice for import of API by Ipram Pharmaceuticals International Rawat Islamabad for the batch No. DCIMCNF063.	The firm has submitted that they have acquired 5Kg of API from M/s Ipram Pharmaceuticals International Rawat Islamabad. The firm has submitted copy of COA vide batch No. DCIMCNF06 Mfg date 10.2021 along with permission letter from DRAP I&E Islamabad in name of M/s IPRAM.
2.	Page 2 of the CoA of the API manufacturer is not legible, hence legible copy needs to be submitted. Justification for performing analysis of API with the innovator brand.	Submitted. Written mistakenly innovator instead of API manufacturer, and has submitted revised batch analysis report.
3.	Justification for performing identification by IR as it is not the requirement of USP monograph and same is not performed by the API manufacturer.	IR identification was written mistakenly in our API COA, revised/corrected COA has now been submitted.
4.	USP monograph states the assay limits for both Cilastatin and Imipenem 90-105%, however your limits are 41.67% to 53.24% as per CoA submitted by you. The requires clarification.	The firm clarified limits for assay showed in the form of potency. Firm has also submitted revised specifications according to USP
5.	3.2.S.4.1The specifications/ assay limits proposed by the API manufacturer in respect of assay are different from the USP monograph, this needs justification.	API manufacturer limits show in the form of separate potencies of Imipenem and Cilastatin but USP monograph shows limits in combine Imipenem/Cilastatin.
6.	3.2.S.4.2The analytical procedures by the API manufacturer needs to be submitted.	Submitted.
7.	3.2.S.5 Certificate of analysis of reference standards for both Imipenem and Cilastatin needs to be submitted	Submitted
8.	3.2.S.7 Legible copies of stability sheets needs to be submitted with	Submitted.

	conclusion on shelf life and storage conditions.	
9.	3.2. P.1 The quantity of API per unit needs to be submitted as per label claim with calculations because the submitted details are not satisfactory.	Frim has submitted revised calculations have been submitted based upon potency.
10.	3.2.P.2.2The Pharmaceutical equivalence study does not reflect the tests for sterility and BET, this needs clarification.	Revised PE study data has been submitted indicating performance of Sterility and BET test.
11.	3.2. P.3 Justification required for manufacturing of three different batches while using the sterile API in one cycle of production. The batch formula need to be clarified with the quantity of API used to manufacture 150 vials on one batch.	150 vials were written mistakenly. The quantity of API used to manufacture product for 500 vials for each trial.
12.	3.2. P.5.2 Analytical procedures for sterility and BET needs to be submitted.	Submitted.
13.	3.2. P.6 CoA's of reference standard	Submitted.
14.	3.2.P.7 Details of container closure system.	Submitted.
15.	3.2.P.8 Clarification required for not performing Sterility and BET during stability.	Revised stability data sheets including results of sterility test & BET test has been submitted.

Decision: Approved.

- **M/s Wallace Pharma Evolutions, shall use 10ml 0.9% NaCl injection as diluent for the commercial batches and submit compatibility study with the 0.9%NaCl solution as diluent.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm shall submit Pharmaceutical equivalence studies against the innovator product before issuance of registration letter.**
- **Registration Board further deciced that registration letter will be issued upon verification of drug substance loan leter by "M/s Ipram International Rawat Islamabad".**

1990.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals Plot No. 387-388 Sector I-9. Industrial Area Islamabad.**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals Plot No. 387-388 Sector I-9. Industrial Area Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20198 dated 15.07.2022
	Details of fee submitted	PKR 75000/- dated 07.07.2022
	The proposed proprietary name / brand name	COLDENOL COLD + FLU SEVERE TABLET
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol….....325mg Dextromethorphan Hydrobromide….10mg Guaifenesin…….200mg

		Phenylephrine HCl….5mg
	Pharmaceutical form of applied drug	Film Coated Tablet
	Pharmacotherapeutic Group of (API)	Antipyretic/ Anti tussive/ Decongestant/ Expectorant
	Reference to Finished product specifications	As per Innovators Specifications
	Proposed Pack size	10's 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tylenol Cold Plus Flu Severe Caplets of Johnson & Johnson USA
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	Copy of inspection report by area FID dated 24.01.2018 indicates good level of GMP.
	Name and address of API manufacturer.	**Paracetamol:** M/s Saakh Pharma Pvt Limited, C-7/1, North Western Industrial zone Port Qasim Karachi. **Dextromethorphan Hydrobromide** M/s Oneiro Chemicals Pvt Limited, S. No. 475/P, at & Post Ekalbara Tal- Padra District Vadodara 391440 Gujarat India. **Guaifenesin** M/s Zhejiang Haizhou Pharmaceuticals Co., Ltd Linhai Industrial Zone, Linhai Zhejiang 317016 China. **Phenylephrine HCl** M/s Shenzhen Oriental Pharmaceutical Co., Ltd, 43 Dakeng Road, Tongle Village Longgang Town, Longgang District Guangdong China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 3 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 3 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure (including dissolution testing) and batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the USFDA OTC Product Tylenol Cold Plus Flu Severe Tablets.

		CDP has been performed against the aforesaid brand in three media. The f2 value are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA			
Manufacturer of API	**Paracetamol:** M/s Saakh Pharma Pvt Limited, C-7/1, North Western Industrial Zone Port Qasim Karachi. **Dextromethorphan Hydrobromide** M/s Oneiro Chemicals Pvt Limited, S. No. 475/P, at & Post Ekalbara Tal- Padra District Vadodara 391440 Gujarat India. **Guaifenesin** M/s Zhejiang Haizhou Pharmaceuticals Co., Ltd Linhai Industrial Zone, Linhai Zhejiang 317016 China. **Phenylephrine HCl** M/s Shenzhen Oriental Pharmaceutical Co., Ltd, 43 Dakeng Road, Tongle Village Longgang Town, Longgang District Guangdong China		
API Lot No.	**Paracetamol:** 19GN60219 **Dextromethorphan Hydrobromide** DX/L/017/018 **Guaifenesin** 18GF09667 **Phenylephrine** PEH-180101Y1		
Description of Pack (Container closure system)	10's 20's & 30's Alu-Alu Blister Packing		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 24 (Months)		
Batch No.	325/10/200/5 Trial No. 1	325/10/200/5 Trial No. 1	325/10/200/5 Trial No. 1
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	02.03.2020	26.03.2020	26.03.2020
Date of Initiation	24.03.2020	17.04.2020	17.04.2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Paracetamol:** GMP certificate issued by DRAP Karachi dated 23.06.2020. **Dextromethorphan Hydrobromide** Copy of DML issued by Commissioner Food & Drug Administration Gandhinagar India. **Guaifenesin** Copy of GMP certificate issued by CFDA China valid till 25.09.2023

		<u>Phenylephrine</u> Copy of GMP certificate issued by Guangdong Food and Drug Administration China dated 12.09.2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copies of DRAP attested invoices for import of Dextromethorphan Hydrobromide, Guaifenesin and Phenylephrine.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Evaluator:
The above product was deferred in 321st meeting of Registration Board for following:

- Evidence of approval of applied formulation as drug in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
- Submission of documents for the procurement of API with approval from DRAP (in case of import).
- Submission of Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

In reply submitted by the firm dated 01.11.2022, the firm informed that Registration Board has already approved the formulation of the products which have OTC status in USFDA. The firm has again submitted the same reference which they have provided previously i.e. Tylenol Cold Plus Flu Severe Caplets of Johnson & Johnson USA. Moreover, the firm has submitted copies of DRAP attested invoices for import of Dextromethorphan Hydrobromide, Guaifenesin and Phenylephrine. Audit trails repost and CFR Compliance certificate is provided by the firm.

Decision: Approved with Innovators specifications.

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

1991.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises (Pvt) Ltd., 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore**
	Details of Drug Sale License of importer	**License No:** 05-352-0058-066904D **Address:** 2nd Floor Plaza 60 Commercial Block-K, Phase 1 DHA Lahore **Address of Godown:** NA **Validity:** 24.02.2023 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., No. 3 Yingbin St. NiuJia Industrial Park South Industrial City Harbin China.
	Name, address of manufacturer(s)	M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., No. 3 Yingbin St. NiuJia Industrial Park South Industrial City Harbin Chine
	Name of exporting country	People's Republic of China

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP No. 20210054 issued by Drug Administration of Heilongjiang Province China on 05.07.2021. Validity: 04.07.2023
	Details of letter of authorization / sole agency agreement	Copy of sole agency agreement is submitted b/w M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., Harbin China. and M/s AMB HK Enterprises (Pvt) Ltd. Lahore
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 32071 dated 23.11.2021
	Details of fee submitted	PKR /-: 150000/- dated 02.11.2021
	The proposed proprietary name / brand name	**SALBIN INHALER**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One metered dose contains: Salbutamol Sulpahte equivalent to 100 micrograms salbutamol.
	Pharmaceutical form of applied drug	Pressurized Inhalation Solution
	Pharmacotherapeutic Group of (API)	Selective beta 2 adrenoceptor agonists/ Bronchodilator
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	Pack of 1 Vial and 1ampoule of 10ml
	Proposed unit price	Rs. 268 for 1's
	The status in reference regulatory authorities	Salamol CFC-Free Inhaler (MHRA)
	For generic drugs (me-too status)	Ventolin Inhaler
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per Module II.
	Name, address of drug substance manufacturer	M/s Heilongjiang Province Fulekang Pharmaceutical Co., Ltd., No. 3 Yingbin St. NiuJia Industrial Park South Industrial City Harbin China.
	Module-III Drug Substance:	Firm has submitted drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, flow diagram of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 60 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, manufacture, manufacturing process

		and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, method validation studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Further the firm has submitted the aerodynamic assessment studies as per BP monograph requirement by Anderson Cascade Impactor.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence is performed with Chinese product manufactured by Shangdong Jewin Pharmaceutical Co., Ltd China.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Aluminum Aerosol Cans & Medicinal Aerosol Valve Package
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40ºC±2ºC and 75%±5% RH for 6 months. Real time stability studies conducted at 30ºC±2ºC and 65% ± 5% for 36 months
	Decision: Deferred for submission of pharmaceutical equivalence studies with innovator drug product.	
1992.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd.** **793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 28.07.2020 by Government of the People's Republic of Bangladesh, Ministry of Health & Family Welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP)

		☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3567 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	Ponatinix 15 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ponatinib Hydrochloride equivalent to Ponatinib…...15mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack of 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Iclusig Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Lianyungang Jari Pharmaceutical Co., ltd No. 18 Zhenhua Road, Lianyungang China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:
Decision in 321st meeting of Registration Board:
Deferred for following points:

i. Justification for conducting Comparative Dissolution studies at "M/s Alpha laboratories India", instead of M/s Beacon Pharmaceuticals Bangladesh.

ii. Regulatory status of Alpha Laboratories India, whether it is licensed entity or otherwise.

In response to the above decision of the Board the firm has submitted the reply on 04.011.2022 which is as under:
The firm has again submitted copy of business agreement dated 04.06.2018 b/w M/s Beacon Pharmaceuticals Bangladesh and M/s Alpha Laboratories India wherein the M/s Alpha Laboratories India shall provide the services being expert in Bioequivalence studies of generic molecules to M/s /s Beacon Pharmaceuticals Bangladesh.

Decision: Deferred for submission of evidence of License/Approval of M/s Alpha Laboratories India, from the relevant regulatory authority of India.

1993.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd.** **793-D, Block C, Faisal Town Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-016174D **Address:** 793-D, Block -C, Faisal Town Lahore **Address of Godown:** NA **Validity:** 06-02-2026 **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh Office Address: 9/B/2, Toyenbee Circular Road, Motijheel, Dhaka, Bangladesh.
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3302) issued on 28.07.2020 by Government of the People's Republic of Bangladesh, Ministry of Health & Family Welfare, Directorate General of Drug Administration Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3567 dated 01.02.2021
	Details of fee submitted	PKR /-: 50,030/- dated 14.12.2020
	The proposed proprietary name / brand name	Ponatinix 45 Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ponatinib Hydrochloride equivalent to Ponatinib…...45mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Anti-Cancer Drug
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack of 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Iclusig Tablets USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s Lianyungang Jari Pharmaceutical Co., ltd No. 18 Zhenhua Road, Lianyungang China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 24 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Iclusig 45mg tablet , Incyte Biosciences UK limited has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE Bottle
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:
Decision in 321st meeting of Registration Board:
Deferred for following points:

i. Justification for conducting Comparative Dissolution studies at "M/s Alpha laboratories India", instead of M/s Beacon Pharmaceuticals Bangladesh.

ii. Regulatory status of Alpha Laboratories India, whether it is licensed entity or otherwise.

In response to the above decision of the Board the firm has submitted the reply on 04.011.2022 which is as under:
The firm has again submitted copy of business agreement dated 04.06.2018 b/w M/s Beacon Pharmaceuticals Bangladesh and M/s Alpha Laboratories India wherein the M/s Alpha Laboratories India shall provide the services being expert in Bioequivalence studies of generic molecules to M/s /s Beacon Pharmaceuticals Bangladesh.

Decision: Deferred for submission of evidence of License/Approval of M/s Alpha Laboratories India,from the relevant regulatory authority of India.

Agenda of Evaluator PEC-XX

Case No. 01 Registration applications of newly granted DML or New section (Human)
New DML
M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
CLB in its 285th meeting held on 17th and 18th March 2022, has considered and approved the grant of DML by way of Formulation with following 3 sections:
Injectable ampoule Section (General)
Capsule Section (General)
Dry powder suspension section (General)
Sachet section (General)
Dry powder vial section (General)

1994.	Name, address of Applicant / Marketing Authorization Holder	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Name, address of Manufacturing site.	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30774 (dated: 31-10-2022)

	Details of fee submitted	PKR 30,000/-: dated: 31-10-2022
	The proposed proprietary name / brand name	Myocin 500mg Dry Powder vial I.V
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride eq. to vancomycin …… 500 mg
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Vancocin injection 500mg USFDA approved
	For generic drugs (me-too status)	Cinva 500mg IV injection by M/s CCl phamaceuticals, Lahore Reg No. 102464
	GMP status of the Finished product manufacturer	Firm has submitted approval letter for DML grant dated 29-04-2022
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd China
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (HAS1507001, HAS1507002, HAS1507003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e. Vancomycin Dry powder vial 500mg by performing quality tests (appearance, volume after reconstitution, identification, Ph after reconstitution, filled volume color, water content, Assay on anhydrous basis, BET, sterility test).		
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.		
STABILITY STUDY DATA				
Manufacturer of API		Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd China		
API Lot No.		HAF 1912013		
Description of Pack (Container closure system)		Glass vial type I with one 10ml glass ampoule of WFI		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		Trail-01	Trail-02	Trail-03
Batch Size		1000 packs	1000 packs	1000 packs
Manufacturing Date		02 – 2022	02 – 2022	02 – 2022
Date of Initiation		28-02-2022	28-02-2022	28-02-2022
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice FXIN2002021A dated **25-02-2020** wherein specifying the import of vancomycin hydrochloride (lyophilized) 30 Kg (batch no HAF 1912013) in the name of M/s Vision pharmaceuticals Islamabad, DRAP clearance certificate and license to import has also been issued in the name of M/s vision pharmaceuticals Islamabad		

	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr.#	Observation	Reply	Remarks
	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has submitted GMP certificate No FJ200003 dated 22.09.2020 valid till 21.09.2022 issued by China Food and Drug Administration	Not complied Valid GMP certificate to be submitted
	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	Gee H20 (5ml) by M/s Gallop Water Sciences.	Not complied Registration No. not provided
	CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is ≥ 900ug/mg while assay limit mentioned in CoA of Drug product manufacturer is 90-115%. Clarify it	It was a drafting error updated CoA as per USP (44) is submitted.	Complied
	Detailed analytical procedures for the testing of drug substance to be provided by both Drug Substance and Drug Product manufacturer	Firm has submitted analytical testing method of Vancomycin HCl by Drug substance manufacturer only	Not complied
	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	Not applicable as the product is immediately used after reconstitution	Not complied In use stability studies are required despite of the fact that formulation is intended to be used immediately after reconstitution
	Documents for the procurement of API (commercial invoice FXIN2002021A dated 25-02-2020, DRAP clearance certificate and license to import) has been issued in the name of M/s vision pharmaceuticals Islamabad. Clarify it.	We are borrowing the material from M/s Vision Pharma. The borrowing undertaking is submitted	Firm has submitted acknowledgement /loan letter from M/s Vision pharmaceuticals Islamabad along with copy of

			commercial invoice attested by DRAP I&E Islamabad dated 20-5-2020
	Proposed container closure system (Glass vial Type 1) suitability testing to be submitted as per pharmacopeia.	Product is as per innovator so suitability testing of Container closure system is not required	Not complied Quality testing of container closure system is required as per USP to assess whether container closure system meets proclaimed criteria i.e USP glass vial type I or not
	Details of manufacturer and batch no of comparator product has not been mentioned under pharmaceutical equivalence study. Also justify selection of that particular comparator product	Vancomycin 1g & 500mg By Getz pharma	Not complied Batch no of comparator products are not provided
	Compatibility studies of drug product with container closure system is not provided.	As the material is ready to fill hence compatibility studies with container closure has been performed by drug substance manufacturer	Not complied Compatibility of the container closure system with the FPP is required as under 2.3.P.2.4 and 3.2.P.2
	Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ master formula.	Updated batch formula/master formula wherein calculation regarding potency adjustment (salt factor and assay result of drug substance) is provided	Complied

Decision: Deferred for submission of followiing:

- **Valid GMP certificate of Drug Substance manufacturer i.e Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd China.**
- **Registration status/ registration number of diluent i.e Gee H20 (5ml) water for injection by M/s Gallop Water Sciences.**
- **Detailed analytical procedures for the testing of drug substance by Drug Product manufacturer.**
- **In use stability data (reconstituted form) to be provided as per guidance document by EMA.**
- **Acknowledgement /loan letter from M/s Vision pharmaceuticals Islamabad.**
- **Suitability testing/Quality testing of Proposed container closure system (Glass vial Type 1) as per pharmacopeia**
- **Batch no of comparator product vancomycin 500mg injection to be provided**

- **Compatibility studies of drug product with container closure system is not provided as required under 2.3.P.2.4 and 3.2.P.2**

1995.	Name, address of Applicant / Marketing Authorization Holder	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Name, address of Manufacturing site.	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30786 (dated: 31-10-2022)
	Details of fee submitted	PKR 30,000/-: dated: 31-10-2022
	The proposed proprietary name / brand name	Myocin 1g Dry Powder vial I.V
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Vancomycin Hydrochloride eq. to vancomycin …… 1g
	Pharmaceutical form of applied drug	Dry powder injection
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Vancocin injection 1g USFDA approved
	For generic drugs (me-too status)	Cinva 1g IV injection by M/s CCl phamaceuticals, Lahore Reg No. 102465
	GMP status of the Finished product manufacturer	Firm has submitted approval letter for DML grant dated 29-04-2022
	Name and address of API manufacturer.	Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd China
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (HAS1507001, HAS1507002, HAS1507003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e. Vancomycin Dry powder vial 1g by performing quality tests (appearance, volume after reconstitution, identification, Ph after reconstitution, filled volume color, water content, Assay on anhydrous basis, BET, sterility test).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd China		
API Lot No.	HAF 1912013		
Description of Pack (Container closure system)	Glass vial type I with one 20ml glass ampoule of WFI		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial-01	Trial-02	Trial-03
Batch Size	1000 packs	1000 packs	1000 packs
Manufacturing Date	03 – 2022	03 – 2022	03 – 2022
Date of Initiation	01-03-2022	01-03-2022	01-03-2022

No. of Batches	03	
Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice FXIN2002021A dated **25-02-2020** wherein specifying the import of vancomycin hydrochloride (lyophilized) 30 Kg (batch no HAF 1912013) in the name of M/s Vision pharmaceuticals Islamabad, DRAP clearance certificate and license to import has also been issued in the name of M/s vision pharmaceuticals Islamabad
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr.#	Observation	Reply	Remarks
	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Firm has submitted GMP certificate No FJ200003 dated 22.09.2020 valid till 21.09.2022 issued by China Food and Drug Administration	Not complied Valid GMP certificate to be submitted
	Regulatory status of diluent (WFI) in Pakistan is required with details of manufacturer and Registration No.	Gee H20 (5ml) by M/s Gallop Water Sciences.	Not complied Registration No. not provided
	CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is ≥ 900ug/mg while assay limit mentioned in CoA of Drug product manufacturer is 90-115%. Clarify it	It was a drafting error updated CoA as per USP (44) is submitted.	Complied
	Detailed analytical procedures for the testing of drug substance to be provided by both Drug Substance and Drug Product manufacturer	Firm has submitted analytical testing method	Not complied

		of Vancomycin HCl by Drug substance manufacturer only	
	In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products en.pdf)	Not applicable as the product is immediately used after reconstitution	Not complied In use stability studies are required despite of the fact that formulation is intended to be used immediately after reconstitution
	Documents for the procurement of API (commercial invoice FXIN2002021A dated 25-02-2020, DRAP clearance certificate and license to import) has been issued in the name of M/s vision pharmaceuticals Islamabad. Clarify it.	We are borrowing the material from M/s Vision Pharma. The borrowing undertaking is submitted	Firm has submitted acknowledgement /loan letter from M/s Vision pharmaceuticals Islamabad along with copy of commercial invoice attested by DRAP I&E Islamabad dated 20-5-2020
	Proposed container closure system (Glass vial Type 1) suitability testing to be submitted as per pharmacopeia.	Product is as per innovator so suitability testing of Container closure system is not required	Not complied Quality testing of container closure system is required as per USP to assess whether container closure system meets proclaimed criteria i.e USP glass vial type I or not
	Details of manufacturer and batch no of comparator product has not been mentioned under pharmaceutical equivalence study. Also justify selection of that particular comparator product	Vancomycin 1g & 500mg By Getz pharma	Not complied Batch no of comparator products are not provided
	Compatibility studies of drug product with container closure system is not provided.	As the material is ready to fill hence compatibility studies with container closure has been performed by	Not complied Compatibility of the container closure system with the FPP is required as under

		drug substance manufacturer	2.3.P.2.4 and 3.2.P.2
	Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ master formula.	Updated batch formula/master formula wherein calculation regarding potency adjustment (salt factor and assay result of drug substance) is provided	Complied

Decision: Deferred for submission of following:

- **Valid GMP certificate of Drug Substance manufacturer i.e Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd China.**
- **Registration status/ registration number of diluent i.e Gee H20 (5ml) water for injection by M/s Gallop Water Sciences.**
- **Detailed analytical procedures for the testing of drug substance by Drug Product manufacturer.**
- **In use stability data (reconstituted form) to be provided as per guidance document by EMA.**
- **Acknowledgement /loan letter from M/s vision pharmaceuticals Islamabad.**
- **Suitability testing/Quality testing of Proposed container closure system (Glass vial Type 1) as per pharmacopeia**
- **Batch no of comparator product vancomycin 1g injection to be provided**
- **Compatibility studies of drug product with container closure system is not provided as required under 2.3.P.2.4 and 3.2.P.2**

1996.	Name, address of Applicant / Marketing Authorization Holder	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Name, address of Manufacturing site.	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30775 (dated: 31-10-2022)
	Details of fee submitted	PKR 30,000/-: dated: 31-10-2022
	The proposed proprietary name / brand name	Ketorol 30mg/ml injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ketorolac Tromethamine……30mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	NSAID

	Reference to Finished product specifications	USP
	Proposed Pack size	5's, 10's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ketorolac Trometamol injection 30mg/ml MHRA approved
	For generic drugs (me-too status)	Toradol injection 30mg/ml by M/s Martin Dow
	GMP status of the Finished product manufacturer	Firm has submitted approval letter for DML grant dated 29-04-2022
	Name and address of API manufacturer.	M/s Saurav Chemicals Ltd, Derabassi Barwala road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (KTM06150007, KTM06150008, KTM06150009)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e. Toradol 30mg/ml injection by performing quality tests (appearance, volume

		claim, Ph, deliverable volume, Assay, BET, sterility test).		
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Saurav Chemicals Ltd, Derabassi Barwala road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India.		
API Lot No.		KTM2100100		
Description of Pack (Container closure system)		Glass type I ampoule (1ml)		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		Trail-01	Trail-02	Trail-03
Batch Size		1000 packs	1000 packs	1000 packs
Manufacturing Date		03 – 2022	03 – 2022	03 – 2022
Date of Initiation		05-03-2022	05-03-2022	05-03-2022
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of DML (No. Pb.2019/3135) dated 11.06.2019 valid till 13.09.2024 issued by Food and Drug Administration, Punjab. India		
	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice SCL/2021-22/331 dated 07-02-2022 wherein specifying the import of Ketorolac Tromethamine (15 Kg (batch no KTM210010) in the name of M/s Global pharmaceuticals Pvt Ltd Islamabad, DRAP clearance certificate and license to import has also been issued in the name of M/s Global pharmaceuticals Pvt Ltd Islamabad.		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.		

Remarks of Evaluator:

Sr.#	Observation	Reply	Remarks
1.	Detailed analytical procedures for the testing of drug substance to be provided by Drug Product manufacturer	Submitted	complied
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non compendial drug substance(s) to be provided	Not submitted 0nly summary report (in tabulated form) is provided	Not complied ***Later on firm has submitted Analytical Method Verification studies including specificity, accuracy and repeatability performed by the Drug Product manufacturer***
3.	Documents for the procurement of API (commercial invoice SCL/2021-22/331 dated 07-02-2022, DRAP clearance certificate and license to import) has been issued in the name of **M/s Global pharmaceuticals Pvt Ltd Islamabad.**. Clarify it.	*We are borrowing the material from* **M/s Global pharmaceuticals Pvt Ltd Islamabad**. *The borrowing undertaking is submitted*	Firm has submitted acknowledgement /loan letter from M/s Global pharmaceuticals Islamabad
4.	Proposed container closure system (Glass ampoule Type 1) suitability testing to be submitted as per pharmacopeia.	*Product is as per innovator so suitability testing of Container closure system is not required*	Not complied Quality testing of container closure system is required as per USP to assess whether container closure system meets proclaimed criteria i.e USP glass type I or not
5.	Details of manufacturer and batch no of comparator product has not been mentioned under pharmaceutical equivalence study. Also justify selection of that particular comparator product	Toradol 30mg/ml injection Manufacturer: Martin Dow Batch No: 25003 Mfg date:07/22 Exp date: 06/24	complied
6.	Compatibility studies of drug product with container closure system is not provided.	*It is evident from stability studies that drug product is compatible with Container Closure system*	Not complied Compatibility of the container closure system with the FPP is required as under 2.3.P.2.4 and 3.2.P.2.
7.	Firm has applied applied the method of "aseptic filtration" for sterilisation of drug product.		

Decision: Approved.

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

1997.	Name, address of Applicant / Marketing Authorization Holder	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Name, address of Manufacturing site.	M/s May and Bakers (Pvt) Ltd, 45 Km, Dina Nath Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30777 (dated: 31-10-2022)
	Details of fee submitted	PKR 30,000/-: dated: 31-10-2022
	The proposed proprietary name / brand name	Doviene 40mg/2ml injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Drotaverine Hydrochloride eq to Drotaverine……40mg
	Pharmaceutical form of applied drug	Solution for injection
	Pharmacotherapeutic Group of (API)	Antispasmodic, Anticholinergic
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	1's, 5's, 10's, 25's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in 3 European countries (Hungary, Romania, Bulgaria)
	For generic drugs (me-too status)	No-spa 40mg/2ml by M/s Snofi pharma
	GMP status of the Finished product manufacturer	Firm has submitted approval letter for DML grant dated 29-04-2022
	Name and address of API manufacturer.	M/s R.A Chem Pharma, Ltd India.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions:

		Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (DTV/116A/2016,DTV/116B/2016,DTV/116C/2016,)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e. No-spa 40mg/2ml by performing quality tests (appearance, volume claim, content uniformity, Ph, deliverable volume, Assay, BET, sterility test).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s R.A Chem Pharma, Ltd India Rs No 50/1 Mukteswarapuram, Krishna District, 521175, India		
API Lot No.	DRO/732/11/19		
Description of Pack (Container closure system)	Amber color glass ampoule (2ml) Type I		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trail-01	Trail-02	Trail-03
Batch Size	1000 packs	1000 packs	1000 packs
Manufacturing Date	03 – 2022	03 – 2022	03 – 2022
Date of Initiation	04-03-2022	04-03-2022	04-03-2022
No. of Batches	03		

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided

	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has recently installed HPLC software 21CFR, in future stability studies shall be performed using HPLC software 21CFR.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Evaluator:

Sr.#	Observation	Reply	Remarks
1.	Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.	Copy of EUDRA GMP certificate no. OGYÉI/21847-4/2022 issued on basis of inspection conducted on 12-04-2022	Complied
2.	Detailed analytical procedures for the testing of drug substance to be provided by Drug Product manufacturer	Submitted	Complied
3.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	COA of the batch No DRO/732/11/19 from Drug Substance / API manufacture and CoA of same batch i.e DRO/732/11/19 from Drug product manufacturer is submitted	Complied
4.	Documents for the procurement of API with approval from DRAP is required Documents for the procurement of API (commercial invoice RAAP/19-20/1533 dated 20-01-2020, DRAP clearance certificate and license to import has been issued (15 kg) batch No DRO/732/11/19 in the name of **M/s Vision Pharma Islamabad.**	*We are borrowing the material from M/s Vision Pharma. The borrowing undertaking is submitted*	Not complied Firm has submitted acknowledgement /loan letter from **M/s Global pharma** rather than M/s vision pharmaceuticals Islamabad. ***Later on firm has provided loan letter from M/s Vision pharmaceuticals Islamabad.***
5.	Proposed container closure system (Glass ampoule Type 1) suitability	*Product is as per innovator so suitability testing of Container*	Not complied Quality testing of container closure system

	testing to be submitted as per pharmacopeia.	*closure system is not required*	is required as per USP to assess whether container closure system meets proclaimed criteria i.e USP glass type I or not
6.	Details of manufacturer and batch no of comparator product has not been mentioned under pharmaceutical equivalence study. Also justify selection of that particular comparator product	No-spa M/s Snofi Aventis Batch No FCB48A Mfg date: 02/2022 Exp date: 01/2025	
8.	Compatibility studies of drug product with container closure system is not provided.	*It is evident from stability studies that drug product is compatible with Container Closure system*	Not complied Compatibility of the container closure system with the FPP is required as under 2.3.P.2.4 and 3.2.P.2
8.	Compatibility of the Drug Substance(s) with excipients is not provided since information regarding excipients used in innovator/reference product is not available.	*Not applicable as we are not using any novel excipient and It is evident from stability studies that drug substance is compatible with excipient*	Not complied Compatibility of the container closure system with the FPP is required as under 2.3.P.2.1 and 3.2.P.2 Since information regarding qualitative composition of excipients of innovator product is not known. ***Later on firm has provided Drug-excipient compatibility study wherein it is concluded that Drotaverine HCl is compatible with all excipients.***
9.	Calculation regarding potency adjustment (salt factor) has not been provided in Batch formula/ master formula.	Updated batch formula/master formula has been provided	Complied

Decision: Approved

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

Case N0. 02 Registration applications of newly granted DML or New section (Human)
New Section:
M/s PDH Laboratories (Pvt) Ltd. 9.5km Sheikhupura Road Lahore

CLB in its 285th meeting held on 07th June 2022, has considered and approved the grant of following additional sections/facility:

Oral Liquid section (General) Additional

1998.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories (Pvt) Ltd. 9.5km Sheikhupura Road Lahore
	Name, address of Manufacturing site.	M/s PDH Laboratories (Pvt) Ltd. 9.5km Sheikhupura Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27451 dated 28/09/2022
	Details of fee submitted	PKR 30,000/-: dated 05/04/2022
	The proposed proprietary name / brand name	Prohis Elixir 120ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Promethazine HCl….5mg
	Pharmaceutical form of applied drug	Elixir
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	BP Specs
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Phenergan Elixir by Sanofi consumer health care in UK (MHRA)
	For generic drugs (me-too status)	Phenergan Elixir 120ml Sanofi Aventis Pakistan Limited Reg #000826
	GMP status of the Finished product manufacturer	Last inspection (renewal of DML) was conducted on 03.01.2020 and 04.01.2022. New additional section for oral liquid syrup (General) was approved dated June 7,2022.
	Name and address of API manufacturer.	Harika Drugs Private Limited Sy. No 165 A & 165/E, Gummadidala Village, Sangareddy District, Telangana State, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Promethazine HCl present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months Batches:(HPHAPB029,HPHAPB030,HPHAPB031)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Phenergan Elixir (batch no. AWO61) 120ml by M/s Sanofi Aventis Pakistan Limited. by performing quality tests (Identification, Assay, pH).
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Harika Drugs Private Limited Sy. No 165 A & 165/E, Gummadidala Village, Sangareddy District, Telangana State, India		
API Lot No.	Not mentioned		
Description of Pack (Container closure system)	Amber glass bottle (USP type III) sealed with aluminium cap		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-005	T-006	T-007
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	14/09/2021	14/09/2021	29/09/2021

No. of Batches	03	
Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No.3390/E1/2019 WHO-GMP certificate issued on 20.11.2019 valid till three years.
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.5201/2020/DRAP-AD-CD(I&E) dated 16/04/2020 is submitted wherein the permission to import different APIs including Promethazine HCl (0.12Kg) for the purpose of test/analysis and stability studies of Promethazine HCl 5mg syrup is granted.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not applicable UV spectroscopic method has been used as per BP.
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Observation	Reply	Remarks
	Detailed analytical procedures for the testing of drug substance to be provided by Drug Product manufacturer	Detailed analytical procedures for the testing of drug substance, provided by Drug Product manufacturer	Complied
	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non compendial drug substance(s) to be provided	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacture, provided	Complied
	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	CoA of Drug Substance for Batch No. HPHCPP021 has been provided from both Drug Substance and Drug Product manufacturer.	Complied
	For testing of Pharmacopeial Drug Substance, the use of primary reference standard is recommended, justify use of working standard for Promethazine HCl	Titrimetric method has been used by API Manufacturer and UV spectroscopic method	

		adopted for finished product (as per BP) Primary Reference standard has been used for characterization and qualification of working standard	
	Documents for the procurement of API with approval from DRAP is required. In already submitted documents batch no/lot no of Drug Substance has not been mentioned.	Batch certification, invoice has been submitted for import of Promethazine HCl (Batch No. HPHCPP021)	Complied
	Suitability testing of proposed container closure system (Glass bottle USP Type III) to be submitted as per pharmacopeia.	Test performed as per USP as follows: Surface glass test Glass grain test Result fall under acceptance limit for USP type III glass.	Complied
	Compatibility studies of drug substance with container closure system is not provided.	As we have performed stability studies in said container closure system for 6 months, the product found stable with no indication for interaction of API with container closure system.	

Decision: Approved

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

Case No. 03 Priority Registration of Vonoprazan (10mg & 20mg) against manufacturing of Paracetamol 500mg tablets

M/s Axis Pharmaceuticals has requested (dated October 28, 2022) to consider Priority evaluation and registration of following products, Form 5F (CTD) as Per 147th meeting of Authority for distribution of 15,000 Packs of Paracetamol in the market:

Vonopra Tablets 10mg 2.Vonopra Tablets 20mg

Manufacturing and distributing data of Axamol Tablet (Paracetamol 500 mg) is tabulated below;

Axamol Tablets Data (From September 20, 2022 to October 26, 2022)						
Sr.#	Batch #	Manufacturing date	Batch Size Packs (200's)	Packs Manufactured (200's)	Tablets Manufactured	*Total Pack sale (21-09-2022 to 25-10-2022) (200's)
1	459	21-09-2022	1250	1240	248000	19268 packs (200's) *All Invoices are attached with this letter
2	460	23-09-2022	1250	1214	242800	
3	461	23-09-2022	1250	1262	252400	
4	462	26-09-2022	1250	1224	244800	
5	463	29-09-2022	1250	1251	250200	
6	464	04-10-2022	1250	1177	235400	

7	465	04-10-2022	1250	1275	255000	
8	466	07-10-2022	1250	1244	248800	
9	467	10-10-2022	1250	1214	242800	
10	468	10-10-2022	1250	1219	243800	
11	469	17-10-2022	1250	1225	245000	
12	470	18-10-2022	1250	1235	247000	
13	471	18-10-2022	1250	1219	243800	
14	472	19-10-2022	1250	1217	243400	
15	473	24-10-2022	1250	1228	245600	
16	474	25-10-2022	1250	1235	247000	
Total				19,679	3,935,800	

1999.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10478 (dated: 25-04-2022)
	Details of fee submitted	PKR 30,000/-: dated: 05-04-2022 (deposit slip# 43031588)
	The proposed proprietary name / brand name	Vonopra Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain: Vonoprazan (as Fumarate) … 10 mg
	Pharmaceutical form of applied drug	Immediate Release Tablet (Coated).
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB)
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablet by Takeda (PMDA approved).
	For generic drugs (me-too status)	Vonseca 10mg tablet by M/s Tabros, Karachi ,Reg No. 112584
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 09-06-2020.

		Section approval letter issued on 30.06.2020
	Name and address of API manufacturer.	Guangdong Xianqiang Pharmaceutical Co. Ltd. Number 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou City, Guangdong Province, China
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph for drug is not present in any pharmacopoeia. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (TAK09R150701, TAK09R150702, TAK09R150703)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e. Vonozan tablet 10mg by Getz Pharma (Batch No 003FF8) by performing quality tests (Average weight, moisture content, Disintegration time, content uniformity Assay, Dissolution,). CDP has been performed against the same brand that is Vonozan tablet 10mg by Getz Pharma (Batch No 003FF8) in pH 1.2, pH 4.5, pH 6.8 and Purified Water. The Average % release of Drug substance in all four mediums is more than 85% at 15 minutes

		hence there is no need to calculate f2 value. The CDP of Vonopra Tablet 10mg against Vonozan Tablet 10mg shows equivalence.		
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.		
STABILITY STUDY DATA				
Manufacturer of API		Guangdong Xianqiang Pharmaceutical Co. Ltd. Guangdong Xianqiang Pharmaceutical Co. Ltd. Number 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou City, Guangdong Province, China		
API Lot No.		B#: TAK09R210401		
Description of Pack (Container closure system)		Alu-PVC blister packed in unit carton.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 3 months Accelerated: 3 months		
Frequency		Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.		T-003	T-004	T-005
Batch Size		2000 Tabs.	2000 Tabs.	2000 Tabs.
Manufacturing Date		12 – 2021	12 – 2021	12 – 2021
Date of Initiation		29-12-2021	29-12-2021	29-12-2021
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Drug manufacturing certificate No Yue20160016 dated 24.12.2020 valid till 23.12.2025 issued by Guandong provincial Drug Administration and GMP certificate (No 20220616) dated 16.06.2022 valid till 15.06.2026		
	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice 13882/2021/DRAP dated 07-09-2021 wherein specifying the import Vonoprazan Fumarate 0.30 Kg. Batch No TAK09R210401		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.		

Remarks of Evaluator:			
Sr.#	Observation	Reply	Remarks
1.	Detailed analytical procedures for the testing of drug substance to be provided by both Drug Substance and Drug Product manufacturer	Provided	Complied
2.	Melting point of Vonoprazan Fumarate is 194.8℃ as per published literature of innovator product while melting point of Drug substance as mentioned in CoA by Drug product manufacturer is 202.3℃ (acceptance limit 200-204℃). Clarify it	As per CoA of drug substance (by API manufacturer) the manufacturer states a melting point range of 200 – 204 ℃ Moreover, as per USP <741> (Melting Range or Temperature) melting range can vary based on factors e.g. sample size, particle size, efficiency of heat of diffusion, etc	Complied Firm has performed FTIR analysis wherein sample has been identified as Vonoprazan fumarate (FTIR spectrum provided)

3.	Justification to be provided for selection of dissolution parameters i.e dissolution medium, acceptance criteria and volume of dissolution medium etc since dissolution test has been performed in purified water only.	*Comparative dissolution profile has been conducted in three BCS media (pH 1.2, 4.5 & 6.8) & purified water Vonoprazan Fumarate has solubility over a broad pH range in aqueous conditions which is expressed in comparative dissolution profile showing more than 85% dissolution within 15 minutes in all dissolution media. Since it's a non-pharmacopoeial product & no data is published regarding dissolution medium in various sites including FDA dissolution data base till now. As the solubility of drug substance is pH independent, therefore Water was selected as dissolution media. Moreover, general parameters for dissolution were selected as per USP <1092> (dissolution procedure development).*	Not complied As per USFDA guidance document for industry Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances, following dissolution parameters to be adopted for highly soluble immediate release tablets: A. **Basket Method (USP apparatus 1)** • Stirring rate = 100 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C B. **Paddle Method (USP apparatus 2)** • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C Moreover, Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of Vonoprazan tablet was 0.05M acetate buffer (pH 4.5) with 50rpm while dissolution medium used by the firm is **water** (900ml) and 50 rpm. Justification to be provided for selection of dissolution medium.
4.	Compatibility of the Drug Substance(s) with excipients is not provided (mainly colloidal Silicon dioxide). Moreover Specifications of colloidal silicon dioxide are also not provided.	Compatibility study of colloidal Silicon dioxide with Drug Substance has been provided The study concludes that there is no incompatibility between the said excipient and API. Moreover, stability study also supports the compatibility study as there is no additional peak observed. Moreover, as the said ingredient is available in BP pharmacopoeia (evidence	Complied

		provided herewith) and is routinely used in oral solid dosage form, therefore	

Decision: Approved

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application**
- **Firm will submit dissolution testing method with revised medium in the light of dissolution parameters selected for evaluation of release profile of Vonoprazan in USFDA approved formulation VOQUEZNA, before issuance of registration letter.**

2000.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B Value Addition City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10478 (dated: 25-04-2022)
	Details of fee submitted	PKR 30,000/-: dated: 05-04-2022
	The proposed proprietary name / brand name	Vonopra Tablet 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contain: Vonoprazan (as Fumarate) … 20 mg
	Pharmaceutical form of applied drug	Immediate Release Tablet (Coated).
	Pharmacotherapeutic Group of (API)	Potassium Competitive Acid Blocker (P-CAB)
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	14's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablet by Takeda (PMDA approved).
	For generic drugs (me-too status)	Vonseca 20mg tablet by M/s Tabros, Karachi ,Reg No. 112585
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 06-07-2020. Section approval letter issued on 30.06.2020

	Name and address of API manufacturer.	Guangdong Xianqiang Pharmaceutical Co. Ltd. Number 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou City, Guangdong Province, China
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph for drug is not present in any pharmacopoeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (TAK09R150701, TAK09R150702, TAK09R150703)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the comparator product i.e. Vonozan tablet 10mg by Getz Pharma (Batch No 004FF9) by performing quality tests (Average weight, moisture content, Disintegration time, content uniformity Assay, Dissolution,). CDP has been performed against the same brand that is Vonozan tablet 10mg by Getz Pharma (Batch No 003FF8) in pH 1.2, pH 4.5, pH 6.8 and Purified Water. The Average % release of Drug substance in all four mediums is more than 85% at 15 minutes hence there is no need to calculate f2 value. The

		CDP of Vonopra Tablet 20mg against Vonozan Tablet 20mg shows equivalence.		
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.		
STABILITY STUDY DATA				
Manufacturer of API		Guangdong Xianqiang Pharmaceutical Co. Ltd. Guangdong Xianqiang Pharmaceutical Co. Ltd. Number 6 Industrial Avenue, Conghua Economic Development Zone, Guangzhou City, Guangdong Province, China		
API Lot No.		B#: TAK09R210401 (QC#: R-456/21)		
Description of Pack (Container closure system)		Alu-PVC blister packed in unit carton.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-003	T-004	T-005
Batch Size		1250 Tabs.	1250 Tabs.	1250 Tabs.
Manufacturing Date		12 – 2021	12 – 2021	12 – 2021
Date of Initiation		29-12-2021	29-12-2021	29-12-2021
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate of Guangdong Xianqiang Pharmaceutical Co. Ltd. The certificate is valid till 19-06-2026.		
	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice 13882/2021/DRAP dated 07-09-2021 wherein specifying the import Vonoprazan Fumarate 0.30 Kg.		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.		

Remarks of Evaluator:

Sr.#	Observation	Reply	Remarks

1.	Detailed analytical procedures for the testing of drug substance to be provided by both Drug Substance and Drug Product manufacturer	Provided	Complied
2.	Melting point of Vonoprazan Fumarate is 194.8℃ as per published literature of innovator product while melting point of Drug substance as mentioned in CoA by Drug product manufacturer is 202.3℃ (acceptance limit 200-204℃). Clarify it	As per CoA of drug substance (by API manufacturer) the manufacturer states a melting point range of 200 – 204 °C Moreover, as per USP <741> (Melting Range or Temperature) melting range can vary based on factors e.g. sample size, particle size, efficiency of heat of diffusion, etc	Complied Firm has performed FTIR analysis wherein sample has been identified as Vonoprazan fumarate (FTIR spectrum provided)
3.	Justification to be provided for selection of dissolution parameters i.e dissolution medium, acceptance criteria and volume of dissolution medium etc since dissolution test has been performed in purified water only.	Comparative dissolution profile has been conducted in three BCS media (pH 1.2, 4.5 & 6.8) & purified water Vonoprazan Fumarate has solubility over a broad pH range in aqueous conditions which is expressed in comparative dissolution profile showing more than 85% dissolution within 15 minutes in all dissolution media. Since it's a non-pharmacopoeial product & no data is published regarding dissolution medium in various sites including FDA dissolution data base till now. As the solubility of drug substance is pH independent, therefore Water was selected as dissolution media. Moreover, general parameters for dissolution were selected as per USP <1092> (dissolution procedure development).	Not complied As per USFDA guidance document for industry Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances, following dissolution parameters to be adopted for highly soluble immediate release tablets: A. **Basket Method (USP apparatus 1)** • Stirring rate = 100 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C B. **Paddle Method (USP apparatus 2)** • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C Moreover, Dissolution medium used in USFDA approved formulation VOQUEZNA for evaluation of release profile of Vonoprazan tablet was 0.05M acetate buffer (pH 4.5) with 50rpm while dissolution medium used

			by the firm is **water** (900ml) and 50 rpm. Justification to be provided for selection of dissolution medium.
4.	Compatibility of the Drug Substance(s) with excipients is not provided (mainly colloidal Silicon dioxide). Moreover Specifications of colloidal silicon dioxide are also not provided.	Compatibility study of colloidal Silicon dioxide with Drug Substance has been provided The study concludes that there is no incompatibility between the said excipient and API. Moreover, stability study also supports the compatibility study as there is no additional peak observed. Moreover, as the said ingredient is available in BP pharmacopoeia (evidence provided herewith) and is routinely used in oral solid dosage form, therefore	Complied

Decision: Approved

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Firm will submit dissolution testing method with revised medium in the light of dissolution parameters selected for evaluation of release profile of Vonoprazan in USFDA approved formulation VOQUEZNA, before issuance of registration letter.**

Case No 04 M/s Horizon Healthcare (Pvt.) Ltd. has requested to consider Priority evaluation and registration of Pytol – C Tablets (dated 19.09.2022) as Per 147th meeting of Authority for consideration of registration applications of Paracetamol containing products on priority. This application was missed from the agenda of 321st meeting (20-22 Sep,2022).

2001.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Sundar Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy.No 26328 dated 19-09-2022
	Details of fee submitted	Rs.75,000/- dated 19-09-2022
	The proposed proprietary name / brand name	Pytol – C Tablets 120mg

<table>
<tr><td></td><td>Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit</td><td>Each chewable tablet contains:
Paracetamol .....120mg</td></tr>
<tr><td></td><td>Pharmaceutical form of applied drug</td><td>Chewable tablet</td></tr>
<tr><td></td><td>Pharmacotherapeutic Group of (API)</td><td>Analgesic and anti-pyretic drug</td></tr>
<tr><td></td><td>Reference to Finished product specifications</td><td>USP</td></tr>
<tr><td></td><td>Proposed Pack size</td><td>2x12’s</td></tr>
<tr><td></td><td>Proposed unit price</td><td>As per SRO</td></tr>
<tr><td></td><td>The status in reference regulatory authorities</td><td>Panadol Chewable Tablets 120mg approved by TGA (Australia)</td></tr>
<tr><td></td><td>For generic drugs (me-too status)</td><td>N/A</td></tr>
<tr><td></td><td>GMP status of the Finished product manufacturer</td><td>Last inspection report dated 14.10.2021 concluded good level of cGMP compliance.</td></tr>
<tr><td></td><td>Name and address of API manufacturer.</td><td>Citi Pharma Limited 3km, Head Balloki Road, Bhai Pheru, Distt Kasur - Pakistan</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td>Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls, Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.</td></tr>
<tr><td></td><td>Module III (Drug Substance)</td><td>The firm as submitted detail of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.</td></tr>
<tr><td></td><td>Stability studies</td><td>Stability study conditions:
Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months
Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
<table>
<tr><td>Batch No</td><td>Accelerated</td><td>Long Term</td></tr>
<tr><td>PGP-14-37</td><td>6 Months</td><td>60 Months</td></tr>
<tr><td>PGP-14-38</td><td>6 Months</td><td>60 Months</td></tr>
<tr><td>PGP-14-36</td><td>6 Months</td><td>60 Months</td></tr>
</table></td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test</td></tr>
</table>

		methods, validation of Analytical methods, Batch analysis , Container closure and stabilities studies.	
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Panadol Chewable 120mg tablet by GSK (Batch No 821121) by performing quality tests (Identification, Assay, disintegration, hardness, content uniformity and Dissolution. CDP has been performed against the same brand that is Panadol Chewable 120mg tablets (Batch No 821121) by GSK in Acid media (pH 1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.	
	Analytical method validation/verification of product	Method verification studies have submitted including Introduction, Verification of assay method, Specificity, Accuracy, Precision, Linearity concentration and range.	
STABILITY STUDY DATA			
Manufacturer of API		Citi Pharma Limited 3.5km, Head Balloki Road, Bhai Pheru, Distt Kasur - Pakistan	
API Lot No.		PGP21-549	
Description of Pack (Container closure system)		Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 6 months Accelerated: 6 months	
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 8, 12, 16, 18, 24(Months)	
Batch No.		ACW-001	ACW-002
Batch Size		5000 Tab	5000 Tab
Manufacturing Date		02-2022	02-2022
Date of Initiation		19-02-2022	19-02-2022
No. of Batches		02	
Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June , 2021. Registration Board decided to approve registration of EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin)	

		Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) by M/s. Horizon Healthcare (Pvt) Ltd. Lahore. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: The HPLC software is 21 CFR compliant. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well. Verification of performance of dissolution test at buffer stage pH 5.5 for Dayzol Capsules 30mg and 60mg. Performance of dissolution test for EMPAZON 10mg and 25mg Tablets with revised specifications i.e not less than 80% (Q) in 15minutes at initial and 01-month time point.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm had provided copy of GMP Certificate of Citi Pharma Limited 3.5km, Head Balloki Road, Bhai Pheru, Distt Kasur Pakistan (Dated 17.12.2022) GMP Valid upto: Two years
	Documents for the procurement of API with approval from DRAP (in case of import).	N/A
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of EvaluatorXX: Firm has submitted specification of hardness as follows: Hardness NLT 4Kp Upper limit to be defined as USFDA recommends that hardness for chewable tablets be kept low (<12 kp). A higher hardness value (>12 kp) may be considered if justified.		
Decision: Deferred for comparison of instant formulation against the innovator product for qualitative composition and manufacturing method applied by firm for masking the bitter effect of drug substance.		

Case No.5 Registration applications of newly granted DML or New section (Human)

New Section:
M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore CLB in its 279th meeting held on 18th February 2021, has considered and approved the grant of following additional section/facility:

Dry Powder for Injection (Cephalosporin) New.

2002.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32619 dated 14.11.2022
	Details of fee submitted	PKR 30,000/- dated 12.10.2022
	The proposed proprietary name / brand name	Jaspime 1gm Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine equivalent to Cefepime ……. 1000mg
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 1g powder for solution for injection Bristol-Myers Squibb Company Princeton, NJ 08543 USA
	For generic drugs (me-too status)	Maxum 1.0gm Injection Curexa Health Pvt LTD, a subsidiary of Highnoon Laboratories Reg. No. 090509
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 26.10.2020 valid till 25/10/2022. New Section Approval granted on 12-03-2021(Dry Powder For Injection Cephalosporin) .
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controlss, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(40003FK86D-A, 40004FK86D-A and 40005FK86D-A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Maxum 1.0gm Injection Curexa Health Pvt LTD, Batch No 2180120 by performing quality tests (Identification, Assay, BET, sterility test, Ph (after reconstitution), particulate matter, diluent volume etc against Jaspime injection 1.0g (Batch No KI-01)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China		
API Lot No.	1011AJ89DB		
Description of Pack (Container closure system)	15ml glass vial with fluorobutyl rubber stopper		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	LH 01	LH 02	LH 03

Batch Size	100Vials	100Vials	100Vials
Manufacturing Date	11-10-2021	11-10-2021	11-10-2021
Date of Initiation	28-10-2021	28-10-2021	28-10-2021
No. of Batches	03		
Administrative Portion			
	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided	
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided	
	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice NO JTRF210911-MQ Verified by DRAP Lahore 14373/204DRAP Dated 24-09-2021.wherein Cefepime HCl with L-Arginine 1000gm has been imported Batch No 1011AJ89DB.	
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided	
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	

Remarks of Evaluator:
1.6.5 Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.
3.2.S.4 CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)
3.2.S.4 Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.
3.2.S.4 The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added reference product (USFDA approved) to control the pH of the constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.
3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture
3.2.P.8 In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products_en.pdf)
3.2.P.8 In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product
3.2.P.1 Provide information including type of diluent, its composition, quantity or volume, specifications Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No.

3.2.P.2 Perform suitability testing of proposed container closure system (Ph.Eur type II glass vial) as per pharmacopeia. 3.2.P.2 Justify selection of that particular comparator product. 3.2.P.2 Compatibility studies of drug product with diluent is not provided. 3.2.P.3 Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ Master formula.
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

2003.	Name, address of Applicant / Marketing Authorization Holder	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Name, address of Manufacturing site.	M/s Jaskan Pharmaceutical Private Limited Plot No 50 Sunder Industrial Estate Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 32618 R&1 DRAP dated 14th Nov.2022
	Details of fee submitted	PKR 30,000/- dated 12.10.2022
	The proposed proprietary name / brand name	Jaspime 500mg injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Cefepime HCl with L-Arginine equivalent to Cefepime ……. 500mg
	Pharmaceutical form of applied drug	Dry powder for solution for Injection
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	USP
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Maxipime 0.5g powder for solution for injection Bristol-Myers Squibb Company Princeton, NJ 08543 USA USFDA approved
	For generic drugs (me-too status)	Cefstar 500 mg Injection By Barrett Hodgson Pakistan Pvt LTD Reg. No. 030953
	GMP status of the Finished product manufacturer	cGMP issued by DRAP based on inspection dated 26.10.2020 valid till 25/10/2022. New Section Approval granted on 12-03-2021(Dry Powder For Injection Cephalosporin)

	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 Dongjia Town Licheng District, Jinan , Shandong, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches:(40003FK86D-A, 40004FK86D-A and 40005FK86D-A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against comparator product Cefstar 500 mg Injection By Barrett Hodgson Pakistan Pvt Ltd Batch No. C5824 by performing quality tests (Identification, Assay, BET, sterility test, Ph (after reconstitution), particulate matter, diluent volume etc against Jaspime injection 1.0g (Batch No LI-01)
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity etc
STABILITY STUDY DATA		
Manufacturer of API	Qilu Antibiotics Pharmaceutical CO, Ltd NO.849 DongJia Town Licheng District, Jinan , Shandong, China	

API Lot No.		1011AJ89DB		
Description of Pack (Container closure system)		15ml glass vial with fluorobutyl rubber stopper		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0,1,2,3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		LI 01	LI 02	LI 03
Batch Size		100 Vials	100 Vials	100 Vials
Manufacturing Date		11-10-2021	11-10-2021	11-10-2021
Date of Initiation		28-10-2021	28-10-2021	28-10-2021
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	Not provided		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice NO JTRF210911-MQ Verified by DRAP Lahore 14373/204DRAP Dated 24-09-2021.wherein Cefepime HCl with L-Arginine 1000gm has been imported Batch No 1011AJ89DB		
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided		
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Evaluator:
1.6.5 Approval of Drug Substance/Drug Manufacturing License (DML)/Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin to be provided.
3.2.S.4 CoA from Drug Product manufacturer is not as per USP. The Assay limit as per USP (44) is 825ug/mg to 911ug/mg (on anhydrous basis) while assay result mentioned in CoA from Drug product manufacturer is 538 ug/mg (on anhydrous basis)
3.2.S.4 Following tests are not mentioned in CoA of Drug Substance (both from Drug Product manufacturer and Drug Substance manufacturer): crystallinity, water determination. Moreover, acceptance criteria for impurity testing is not as per USP.
3.2.S.4 The L-arginine, at an approximate concentration of 725 mg/g of cefepime, is added in reference product (USFDA approved) to control the pH of the constituted solution at 4.0–6.0. Calculation of arginine quantity in bulk powder to be provided.
3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance (Batch No 1011AJ89DB) performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture

3.2.P.8 In use stability data (reconstituted form) to be provided as per guidance document by EMA. (https://www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-use-stability-testing-human-medicinal-products_en.pdf) 3.2.P.8 In stability testing Pharmacopoeial tests like BET, sterility test, water determination and uniformity of dosage unit has not been performed. 3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports on product 3.2.P.1 Provide information including type of diluent, its composition, quantity or volume, specifications Regulatory status of diluent in Pakistan is required with details of manufacturer and Registration No. 3.2.P.2 Perform suitability testing of proposed container closure system (Ph.Eur type II glass vial) as per pharmacopeia. 3.2.P.2 Justify selection of that particular comparator product. Moreover pharmaceutical equivalence study against Jaspime 500mg injection has not been performed (instead Jaspime 1000mg injection was used against Cefstar 500 mg Injection) 3.2.P.2 Compatibility studies of drug product with diluent is not provided. 3.2.P.3 Calculation regarding potency adjustment (salt factor and assay result of drug substance) has not been provided in Batch formula/ Master formula.
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Case. No. 01: Request of M/s Aries Pharmaceuticals (Pvt) Ltd, Peshawar for Correction in Label Claim/ Pack Size of Aricain Injection 10mg/ml.

Registration Board in its 320th meeting held on 29th -31st August, 2022 approved registration of Aricain Injection 10mg/ml in the name of M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar as per following details:

1.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k
	Brand Name +Dosage Form + Strength	Aricain **10mg/ml** Injection
	Composition	Each **1ml** Ampoule Contains: Lidocaine Hcl…10mg
	Diary No. Date of R& I & fee	Dy.No. 14373 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Local anaesthetic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lidocaine Injection 1% w/v (MHRA approved)
	Me-too status (with strength and dosage form)	Lacain 1% Injection of M/s. Pulse Pharmaceuticals
	GMP status	cGMP certificate on the basis of Evaluation conducted on 06-04-2022 and valid for two (02) Years.
	Previous remarks of the Evaluator.	
	Previous decision(s)	**Deferred for following reasons:** Deferred for consideration on its turn. **(M-296)**
	Remarks of the Evaluator.	
	Decision of M-320: Approved with USP Specifications.	

Now, the firm has informed that their applied pack size was **"2ml"** instead of **"1ml"** and also submitted a fee of Rs.30,000/- (Invoice # 60746612949), verified from https://fee.dra.gov.pk/admin#/search/slip for change in pack size and accordingly in label claim. Correct pack size and label claim are as under:

"Aricain Injection 20mg/2ml
Each 2ml ampoule contains:
Lidocaine Hydrochloride……...20mg"

Proceedings of M-323:

Registration Board was apprised that there is no change in strength of the product i.e., 1% Lidocaine Hydrochloride. However, label claim will be mentioned in accordance the correct pack size i.e., "2ml"

Decision: Registration Board approved correction in pack size/ label claim of above-mentioned product as per following detail:
"Aricain Injection 1%
Each 2ml ampoule contains:
Lidocaine Hydrochloride……..20mg
(USP Specifications)"

Case. No. 02: Request of M/s Barrett Hodgson Pakistan (Pvt) Ltd, Karachi for Correction in Label Claim of Lincostar 500mg Capsule

Registration Board in its 293rd meeting held on 06th-08th January, 2020 approved registration of Lincostar Capsule 500mg in the name of M/s Barrett Hodgson Pakistan (Pvt) Ltd, F/423, S.I.T.E., Karachi as per following details:

1.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Lincostar Capsule **500mg**
	Composition	Each capsule contains: Lincomycin as HCl monohydrate….**20mg**
	Diary No. Date of R& I & fee	Dy No. 27715: 13.08.2018 PKR 20,000/-: 13.08.2018
	Pharmacological Group	Lincosamides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	12's; Rs. 180/-
	Approval status of product in Reference Regulatory Authorities.	Lincocine 500 mg capsule (Lincomycin as HCl hydrate) by Pfizer Holding France. Approved by ANSM France
	Me-too status	Linnco 500mg Capsule (Lincomycin as HCl) by Mafins Pharmaceuticals (Pvt) Ltd., Karachi. Reg. No. 79898
	GMP status	The firm was inspected on 16th-28th August, 2018 Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator.	• Form 5 has been signed by person from medical and regulatory department of the firm. • The USP has specified Raman spectroscopy for dissolution study of Lincomycin capsules. The firm was asked to provide proof of provision of Raman spectrophotometer. The firm replied that they will arrange the same. • The firm was asked to revise the API to Lincomycin as HCl monohydrate in label claim. The firm replied that they will revise the same.
	Prevoius decision	The Board in its 292nd meeting deferred the case for: • Proof of provision of Raman spectrophotometer. • Revision of the API to Lincomycin as HCl monohydrate in label claim • Signature of rrespective persons.
	Evaluation by PEC	• The firm has claimed BP specifications. • **The firm has revised the API to Lincomycin as HCl monohydrate in label claim.** • **The firm has submitted Rs. 5000/- fee.** • The firm has submitted revised form 5.
	Decision: Approved.	

Registration letter could not be issued due to disparity in strengths mentioned in composition and alongside the brand name. In this context original dossier could not be retrieved from available record, however, the firm has submitted copies of DRAP's acknowledged receipts, form-5 & fee challan of above-mentioned product, all stating strength of **"500mg"** instead of **"20mg".** Accordingly, the firm has requested for correction in label claim of above-mentioned product.
In this regard, it has been observed from minutes of 293rd meeting that **the firm revised the API to Lincomycin as HCl monohydrate in label claim with fee of Rs.5000/-**. Accordingly, the firm may be directed to submit differential fee of Rs.25000/- before issuance of registration letter.

Decision: Registration Board decided as under:

i. **Approved correction in strength/ label claim of above-mentioned product as per following detail:**

   "Lincostar Capsule 500mg
   Each capsule contains:
   Lincomycin as Hydrochloride Monohydrate……...500mg
   (USP Specifications)"

ii. **The applicant shall submit differential fee of Rs. 25,000/- in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 for pre-registration variation/ correction in composition/label claim in line with that approved by reference regulatory authorities.**

Case. No. 03: Request of M/s CSH Pharmaceuticals-North (Pvt) Ltd., Peshawar for Correction in Minutes of 282nd Meeting of Registration Board

Registration Board in its 282nd meeting held on 14th – 15th May, 2018 approved registration of Injectacef IV 500mg Injection in the name of M/s Astellas Pharmaceuticals (Pvt) Ltd., 15-C, Hayatabad Industrial Estate, Peshawar as per following details:

Name and address of manufacturer / Applicant	M/s ASTELLAS Pharmaceutical, Peshawar
Brand Name +Dosage Form + Strength	INJECTACEF IV 500mg Injection
Composition	Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…….500mg
Diary No. Date of R& I & fee	8145, 10-07-2017, 20,000/-, 07-07-2017
Pharmacological Group	3rd Generation cephalosporin antibiotic
Type of Form	Form-5
Finished product Specification	In house specification
Pack size & Demanded Price	1's;As per SRO
Approval status of product in Reference Regulatory Authorities.	Rocephin IV 500 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd, MHRA
Me-too status	Signum 500 mg Injection I.V by M/s Cherwel Pharmaceuticals (Pvt) Ltd (Reg#079307)
GMP status	Routine GMP inspection dated 02-10-2017 overall the firm was operating under satisfactory level of cGMP.
Remarks of the Evaluator.	
Decision: Approved with USP specifications.	

M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A Industrial Estate, Hayatabad Peshawar has requested for correction in minutes of 282nd meeting stating that the above-mentioned product was applied by them through contract manufacturing at M/s Astellas Pharmaceuticals (Pvt) Ltd., 15-C, Hayatabad Industrial Estate, Peshawar.

In this context original dossier could not be retrieved from available record, however, in this regard the firm has submitted following supporting documents:

i. Copy of DRAP endorsed receipt of registration application received on 10-07-2017 and Form-5, both stating/indicating particulars of contract manufacturing at M/s Astellas Pharmaceuticals (Pvt) Ltd. Peshawar. Furthermore, copy of fee challan (#0709067) of Rs.50000/- states M/s CSH Pharmaceuticals North (Pvt) Ltd., (DML No. 000511) as name of firm.
ii. Copy of approval letter issued to M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A Industrial Estate, Hayatabad Peshawar for extension in contract manufacturing of **"Injectacef 250mg and 1g Injection"** at M/s Astellas Pharmaceuticals (Pvt) Ltd. Peshawar (valid till June, 2025).
iii. Copy of last inspection report of M/s Astellas Pharmaceuticals (Pvt) Ltd. Peshawar dated 06-07-2021 (indication "Good" level of compliance)
iv. Copy of approval of "Dry Powder Injection (Cephalosporin) Section" issued by Licensing Division vide letter dated 17-09-2021.
v. Contract manufacturing agreement.

Decision: Registration Board decided as under:

i. Approved correction in minutes of 282nd meeting with respect to approval of "Injectacef IV 500mg Injection" as per following detail:

Product Name & Composition	**Applicant/ Contract Giver**	**Manufacturer/ Contract Acceptor**
Injectacef IV 500mg Injection **Each vial contains:** **Ceftriaxone Sodium Eq. to Ceftriaxone…….500mg**	**M/s CSH Pharmaceuticals-North (Pvt) Ltd., 38-A Industrial Estate, Hayatabad Peshawar**	**M/s Astellas Pharmaceuticals (Pvt) Ltd., 15-C, Hayatabad Industrial Estate, Peshawar.**

ii. The applicant shall submit fee of Rs. 7500/- in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 for pre-registration variation/ change in finished product specifications from "In house Specifications" to "USP Specifications".

Case. No. 04: Request of M/s Lisko Pakistan (Pvt) Ltd., Karachi for Correction in Strength/ Label Claim of Glucomin 50mg/1000mg Tablet Approved in 285th Meeting of Registration Board

Registration Board in its 285th meeting held on 03rd-04th October, 2018 approved registration of Glucomin 50/1000mg Tablet in the name of M/s Lisko Pakistan (Pvt) Ltd. L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi as per following details:

Name and address of manufacturer / Applicant	M/s Lisko Pakistan (Pvt) Ltd. L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
Brand Name +Dosage Form + Strength	Glucomin 50mg/**1000mg** Tablet
Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate) ……50mg Metformin hydrochloride……**850mg**
Diary No. Date of R& I & fee	Dy.No.13665; 28-08-2017; Rs.20,000/- (25-08-2017)
Pharmacological Group	Antihyperglycemic
Type of Form	Form-5

Finished product Specification	Manufacturer's specifications
Pack size & Demanded Price	10's, 14's, 30's ; As per SRO
Approval status of product in Reference Regulatory Authorities.	Janumet tablets of (TGA approved)
Me-too status (with strength and dosage form)	S-Gliptin Plus Tablets of M/s Barrett Hodgson
GMP status	Last GMP inspection is conducted on 24- 04- 2018 and the report concludes that overall firm has satisfactory level of GMP compliance.
Previous remarks of the Evaluator.	
Previous decision(s)	Deferred for following reasons: Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies. **(M-283)**
Evaluation by PEC	FID verified 2 stability chamber 1 for Accelerated stability studies and 1 for Real time stability studies.
Decision: Approved with innovator's specification.	

Registration letter could not be issued due to disparity in strengths mentioned in composition and alongside the brand name. In this context original dossier could not be retrieved from available record, however, the firm has submitted copies of DRAP's acknowledged receipt, form-5 & fee challan of above-mentioned product, all stating strength of **"50/1000mg"** instead of **"50/850mg".** Furthermore, the firm has submitted an undertaking that they applied for registration of only two strengths (i.e., 50/500mg & 50/1000mg) of above formulation and registration of 50/500mg tablet has already been issued (R#092900). Accordingly, the firm has requested for correction in strength/ label claim of above-mentioned product from **"50/850mg"** to **"50/1000mg".**

Decision: Registration Board decided as under:

i. **Approved correction in strength/ label claim of above-mentioned product as per following detail:**

"Glucomin 50mg/1000mg Tablet
Each film coated tablet contains:
Sitagliptin (as Phosphate Monohydrate) ……50mg
Metformin Hydrochloride……..…1000mg"

ii. **The applicant shall submit fee of Rs. 7500/- in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 for pre-registration variation/ change in finished product specifications from "Manufacturer's Specifications" to "As per Innovator's Specifications".**

Case. No. 05: Correction in Strength/ Label Claim of Aultazole 50mg/5ml Suspension Approved in 307th Meeting of Registration Board

Registration Board in its 307th meeting held on 08th – 10th June, 2021 approved registration of Aultazole 50mg/5ml Suspension in the name of M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V, industrial Estate, Hattar as per following details:

Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V, industrial Estate, Hattar
Brand Name +Dosage Form + Strength	Aultazole **50mg / 5ml** Suspension
Composition	Each **5ml** after reconstitution contains: Fluconazole……..**10mg**
Diary No. Date of R& I & fee	14927, 07-03-2019, 20,000/-, 07-03-2019

Pharmacological Group	Antifungal
Type of Form	Form-5
Finished product Specification	BP specifications
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
Me-too status	Zefung Dry Powder Suspension of Nexus Pharma
GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Oral Powder suspension (General) section
Previous remarks of the Evaluator.	Fee challan does not specify brand name, strength and dosage form of applied product. Only API is written as Fluconazole. Label claim and master formulation does not suggest Dry powder suspension. Revision of Form-5 is required.
Previous decision(s)	Deferred for revision of formulation as per reference product alongwith submission of applicable fee (M-289). Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation (M-292).
Evaluation by PEC	The firm has submitted revised Form-5 from liquid suspension to Dry powder suspension alongwith submission of fee challan of Rs. 5,000/- (deposit slip # 1914386) dated 18-07-2019. Fee challan of Rs. 15,000/- (deposit slip # 2044990) dated 25-01-2021 has been submitted.
Decision: Approved.	

Registration letter could not be issued due to disparity in strengths mentioned in composition and alongside the brand name. In this context original dossier could not be retrieved from available record, however, the firm has submitted copies of DRAP's acknowledged receipts, form-5 & fee challan of above-mentioned product, all stating strength of **"50mg/5ml"** instead of **"10mg/5ml".** Accordingly, the case has been placed for correction in strength/ label claim of above-mentioned product.

Decision: Registration Board decided as under:

i. **Approved correction in strength/ label claim of above-mentioned product as per following detail:**

"Aultazole Powder for Suspension 50mg/ 5ml
Each 5ml after reconstitution contains:
Fluconazole……..……..50mg
(BP Specifications)"

ii. **The applicant shall submit differential fee of Rs. 10,000/- in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 for pre-registration variation/ correction in dosage form from "Liquid Suspension" to "Powder for Suspension" in line with that approved by reference regulatory authorities.**

Case. No. 06: Request of M/s Sanofi-Aventis Pakistan Limited, Karachi for License Withdrawal of Largactil Injection (Reg. No.001218) & Largactil Syrup (Reg. No.000819)

M/s Sanofi-Aventis Pakistan Limited, Plot No.23, Sector 22, Korangi Industrial Area, Karachi has requested for license withdrawal of following products:

S/N	Reg. No.	Brand name and composition	Justification	Alternate Brands	Date of Reg. & Last Renewal Status
I	II	III	IV	V	VI
1.	001218	**Largactil Injection** [Composition as per National Formulary: Chlorpromazine Hydrochloride 25mg(2.5%)]	The product has no demand and better molecules are available in market. Furthermore, the decision is not related to safety, quality and efficacy.	➢ Modecate (Fluphenazine) Injection of Glaxosmith Pharma ➢ Clopixol (Zuclopenthixol) Injection of M/s Lundbeck Pharma ➢ Dosik (Haloperidol) Syrup of M/s Adamjee.	DOR: 14-07-1976 (M/s May & Baker Ltd, Mandviwallas Chambers, Karachi) Transfer of Reg: 25-10-1993 (M/s Rhone-Poulance Pakistan (Pvt) Ltd, Wah Cantt) 21-01-2004 (M/s Aventis Ltd, Karachi) 28-07-2006 (M/s Sanofi-Aventis (Pakistan), Wah Cantt. Last Renewal 03-06-2016
2.	000819	**Largactil Syrup** (Composition as per National Formulary: Chlorpromazine Hydrochloride 25mg)	The product has no demand and better molecules are available in market. Furthermore, the decision is not related to safety, quality and efficacy.	➢ Modecate Injection of Glaxosmith Pharma ➢ Clopixol Injection of M/s Lundbeck Pharma ➢ Dosik Syrup of M/s Adamjee.	DOR: 14-07-1976 (M/s May & Baker Ltd, Mandviwallas Chambers, Karachi) Transfer of Reg: 25-10-1993 (from M/s Rhone-Poulance Pakistan (Pvt) Ltd, Wah Cantt to M/s Rhone-Poulance Rorer Pakistan (Pvt)

					Ltd, Wah Cantt) 21-01-2004 (M/s Aventis Ltd, Karachi) 28-07-2006 (M/s Sanofi-Aventis (Pakistan), Wah Cantt. 27-03-2009 M/s. Sanofi Aventis,Wah to M/s. Sanof-Aventis Karachi) <u>Last Renewal 04-03-2019</u>
Documents submitted by the firm in the light of SOP approved vide 283rd meeting of Registration Board. (No fee has been submitted)			a. Copy of Registration Letters. b. List of alternate brands available in the country. c. Justification. d. An Undertaking that: i. No case is pending at any forum/ court of law regarding above mentioned products. ii. Provided information/ documents are true/ correct.		

Decision: **Registration Board did not accede to the request of M/s Sanofi-Aventis Pakistan Limited, Karachi for license/registration withdrawal of Largactil Injection (Reg. No.001218) and Largactil Syrup (Reg. No.000819). The Board further decided as under:**

i. **Renewal status of the products will be confirmed from RRR section and accordingly registration holder will be directed to continue manufacturing in compliance with the Conditions of Registrations under Rule 30 of Drugs (L, R & Advertising) Rules, 1976 and also ensure regular and adequate supply of above-mentioned products to avoid their shortage in the market.**

ii. **The matter will also be deliberated with "Committee on Availability of Life Saving Drugs" and outcome will be shared with Registration Board for consideration.**

Case No.07. Request of M/s Novartis Pharma (Pakistan) Limited, Karachi for De-Registrations of Rimactal Syrup 2% (Reg.No.021521).

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf Dockyard Road, Karachi has requested for de- registrations of their following product:

S/N	Reg. No.	Brand Name and Composition [Fee Detail]	Justification	Alternate Brands	Date of Reg.
I	II	III	IV	V	VI

1.	021521	Rimactal Syrup 2% Each 100ml contains: Rifampicin…….2mg (Manufacturer Specifications) Fee: Rs.7500/- Invoice # 853694867	Due to global directives the firm has divested this portfolio in Pakistan.	1. Afracin by M/s CCL Pharmaceutical 2. Rifamed by M/s Medicena Pharma 3. Rifampicin by M/s Geofman	13-02-2020 on contract basis for a period of 30months.
Documents submitted by the firm in the light of SOP approved vide 283rd meeting of Registration Board.			a. Copy of Registration Letters. b. List of alternate brands available in the country. c. Justification. d. An Undertaking that: i. No case is pending at any forum/ court of law regarding above mentioned products. ii. Provided information/ documents are true/ correct.		

Decision: **Registration Board did not accede to the request of M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf Dockyard Road, Karachi for de-registration of Rimactal Syrup 2% (Reg. No. 021521). The Board further decided as under:**

i. **Renewal status of the product will be confirmed from RRR section and accordingly registration holder will be directed to continue manufacturing (after correction in label claim from 2mg/100ml to 20mg/100ml) in compliance with the Conditions of Registrations under Rule 30 of Drugs (L, R & Advertising) Rules, 1976 and also ensure regular and adequate supply of above-mentioned product to avoid its shortage in the market.**

ii. **The matter will also be deliberated with "Committee on Availability of Life Saving Drugs" and outcome will be shared with Registration Board for consideration.**

Case No.08: Request of M/s Akhai Pharmaceuticals (Pvt) Ltd., Balochistan for Manufacturing of Ketlar Injection 500mg/ml (Reg.No. 014966) to Consume the Available API

M/s Akhai Pharmaceuticals (Pvt) Ltd., A-248 & A-256 to A-259, Hub Industrial Trading Estate Lasbella Balochistan has informed that they have contract manufacturing permission (valid till 30th June, 2025) of Ketlar Injection (Reg. No.014966) by M/s. Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupra Road, Lahore.

The firm has further informed that the contract manufacturer i.e. M/s Neutro Pharma had imported 50kg of Ketamine HCl on their behalf and for the exclusive manufacturing of their above stated product. Primary and secondary packaging materials are also available with them. However, Ketamine has recently been classified under controlled substances. Now there is acute shortage in the market and patient is suffering due to non-availability of this essential drug. Accordingly, the firm has requested for permission to consume the available quantity of Ketamine HCl in the best interest of patient.

In this context, it is submitted that Ketamine and its salts has been declared as "Psychotropic substances" vide SRO Number 1350(I)/2021 dated 15th October, 2021. Furthermore, as the existing contract manufacturing policy, notified vide SRO 1347(I)/2021, dated 15.10.2021, Rule 20 A 2(c):

"Contract manufacturing of controlled drugs (narcotic drug or psychotropic substances or precursor chemicals) shall not be allowed;"

However, the above referred product was granted registration for contract manufacturing well before classification of Ketamine under controlled substances.

Comments Received from Controlled Drugs Division:

The Committee for Allocation of Quota of Controlled Substances allocates the quota to those firms having valid drug manufacturing license and valid drug registration as per SOP.

Comments Received from QA&LT Division:

Consumption of any API is linked primarily to valid license to manufacture a drug and secondarily to valid registration of that drug. If as a consequence of any change in some rule/regulation or policy the status of both these prerequisite (DML and MA) for any drug becomes void/invalid, the consumption of respective APIs could not be allowed for that particular drug.

Decision: Keeping in view the classification of "Ketamine and its salts" under psychotropic substances (vide SRO 1350(I)/2021 dated 15th October, 2021) and Rule 20A(2)(c) of Drugs (L, R & A), Rules, 1976, Registration Board decided as follows:

- **Decided to issue show cause notice to the firm under Section 7 (11)(d) of the Drug Act, 1976 that why the registration of their product "Ketlar Injection (Reg. No. 014966)" may not be cancelled. Management of the firm shall also be given the opportunity of personal hearing in the forthcoming meeting of the Board under section 42 of the Drugs Act, 1976.**
- **Recommended QA&LT Division to decided case for already imported material as per Drug (I&E) Rules, 1976.**

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Case No.09. Request of M/s Martin Dow Marker Limited, Quetta for import of Controlled Drug Substances for Trial/ Development & Stability Purposes.

M/s Martin Dow Marker Limited, 7, Jail Road, Quetta has requested for import of different controlled drug substances for trial, development and stability purposes. Detail is as under:

i. Midazolam Injection 5mg/5ml:

S. No.	Controlled Drug Substance	Quantity required for trial development and stability batches	Source
1.	Midazolam Injection 5ml (5mg/5ml)	21.05g	Fabbrica Italiana Sintetici S.p.a, Italy
Total			
2.	Midazolam Reference Standard	300mg	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S/N	Product	API	mg/ mL	No. of Bottles/batch	No. of batches	Quantity of API required		
1.	**Midazolam Injection 5ml**	Midazolam	5mg/ 5ml	Development Batch: (800 Ampoules) Stability Batch:01 (800 Ampoules) Stability Batch :02 (800 Ampoules) Stability Batch:03 (800 Ampoules)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batch (01) Stability batches (3)	4.00 + 12.00 :16g	**A.** Chemical testing: Retention Sample: 2g **B.** chemical	21.05g

							testing 3.05g A+B= 5.05g	

Testing Interval		**Quantity of Trial Batch Sample Required for Testing**	**Remarks**
Initial		150 ml	Initial testing include sterility and BET testing as well
3rd Month	Real Time	20 ml	N/A
	Accelerated	20 ml	N/A
6th Month	Real Time	20 ml	N/A
	Accelerated	20 ml	N/A
9th Month	Real Time	20 ml	N/A
12th Month	Real Time	135 ml	12th month testing include sterility and BET testing as well
18th Month	Real Time	20 ml	N/A
24th Month	Real Time	135 ml	12th month testing include sterility and BET testing as well
Total Sample Required for Stability Testing		**540 ml/ batch = 108 Ampoules/ batch**	

ii. <u>Diazepam Injection 10mg/2ml:</u>

S. No.	**Controlled Drug Substance**	**Quantity required for trial development and stability batches**	**Source**
1.	Diazepam Injection 2ml (5mg/ml)	86.06g	Fabbrica Italiana Sintetici S.p.a, Italy
Total			
2.	Diazepam Reference Standard	200mg	
3.	Diazepam Related Compound A	50mg	
4.	Diazepam Related Compound B	50mg	
5.	USP Nordazepam RS	50mg	

S/N	**Product**	**API**	**mg/ mL**	**No. of Bottles/batch**	**No. of batches**	**Quantity of API required**		
1.	**Diazepam Injection 2ml**	Diazepam	5mg/ ml	Batch size for trial Development batch: (2000 Ampoules) Stability batch:1 (2000 Ampoules) Stability Batch:2 (2000 Ampoules)	Trial + Stability	For Formulation Development	For QC testing & Retention	Total
						g	g	g
					Trial batches (01)	20g + 60g Total:	**A.** Chemical testing:	86.06g

				Stability Batch: 3 (2000Ampoules)	Stability batches (3)	80g	Retention Sample: 2g **B.** chemical testing: 4.06g A+B= 6.06g	

Testing Interval		**Quantity of Trial Batch Sample Required for Testing**	**Remarks**
Initial		80 ml	Initial testing include sterility and BET testing as well
3rd Month	Real Time	20 ml	N/A
	Accelerated	20 ml	N/A
6th Month	Real Time	20 ml	N/A
	Accelerated	20 ml	N/A
9th Month	Real Time	20 ml	N/A
12th Month	Real Time	66 ml	12th month testing include sterility and BET testing as well
18th Month	Real Time	20 ml	N/A
24th Month	Real Time	66 ml	12th month testing include sterility and BET testing as well
Total Sample Required for Stability Testing		**332 ml / batch = 166 Ampoules/ batch**	

iii. <u>Clonazepam Drops 25mg/10ml:</u>

S. No.	**Controlled Drug Substance**	**Quantity required for trial development and stability batches**	**Source**
1.	Clonazepam Oral Drops 0.25% (2.5mg/ml)	47.3g	Fabbrica Italiana Sintetici S.p.a, Italy
Total			
2.	Clonazepam Reference Standard	400mg	
3.	Clonazepam Related Compound A	25mg	
4.	Clonazepam Related Compound B	25mg	
5.	Clonazepam Related Compound C	25mg	

S/N	**Product**	**API**	**mg/ml**	**No. of Bottles/batch**	**No. of batches**	**Quantity of API required**		
1.	**Clonazepam Liquid Drops 25mg/10ml**	Clonazepam	2.50	Development Batch: (400 Bottles) Stability Batch:01	Trial + Stability	For Formulation Development	For QC testing & Retention	Total

				(400 Bottles) Stability Batch :02 (400 Bottles) Stability Batch:03 (400 Bottles)		g	g	g
					Trial batches (01) Stability batches (03)	10.00g+ 30.00g Total: 40.00g	**A.** Chemical testing: Retention Sample: 2g **B.** chemical testing: 5.3g A+B= 7.3g	47.3g

Testing Interval		**Quantity of Trial Batch Sample Required for Testing**	**Remarks**
Initial		100 ml	Initial testing include bioburden test as well
3rd Month	Real Time	20 ml	N/A
	Accelerated	20 ml	N/A
6th Month	Real Time	20 ml	N/A
	Accelerated	20 ml	N/A
9th Month	Real Time	20 ml	N/A
12th Month	Real Time	100 ml	12th month testing include bioburden test as well
18th Month	Real Time	20 ml	N/A
24th Month	Real Time	100 ml	12th month testing include bioburden test as well
Total Sample Required for Stability Testing		**420 ml / batch = 42 Bottles/ batch**	

In support of their request, the firm has also submitted following information/ documents:

1. Fee of Rs.7500/each (S#01113943330, 1275025823 and 1054657968)
2. The firm has submitted approval letter of layout plan for New /Additional Section of Liquid Oral Drops (Psychotropic) and Liquid Injection Ampoule (Psychotropic) under DML No.000028 (Formulation) (Reference Letter F.No.4-2/86-Lic (Vol-III)-Pt dated 23-05-2022.
3. The firm has further informed that till establishment of requisite manufacturing facility, they will manufacture the trial and stability batch of drug product in NPD, which is approved facility from DRAP. Consequent to successive establishment of Liquid Oral Drops (Psychotropic) facility and grant of section by DRAP, they will be able to apply for product registration on the basis of completion of stability studies on CTD together with section approval letter. Afterwards, based on registration they will be capable to generate the commercial drug product at designated area.
4. Undertaking that the firm will comply the time plan for the construction of requisite sections for which layout plan has been approved vide Licensing Division's letter No.F.4-2/86-Lic (Vol-VII)-Pt issued on dated 23-05-2022.

5. The firm has further informed that the above-mentioned quantities of APIs have been requested keeping in view the minimum capacity of the equipment (e.g., 4L is the minimum capacity in case of liquid injectables) and to successfully accomplish whole formulation development, analysis & stability studies parameters.

Decision: Registration Board decided as under:

i. **Recommended the allocation of controlled drug substance(s) i.e., Midazolam, Diazepam and Clonazepam along-with their reference standard(s) and related compound(s) for trial, development & stability batches of above-mentioned products.**
ii. **The firm shall be advised to maintain records of used substances and waste materials having above APIs and same shall be destroyed after approval of Controlled Drugs Division, DRAP.**
iii. **Marketing Authorization / registration to M/s Martin Dow Marker Limited, 7, Jail Road, Quetta shall be granted as per applicable policy regarding Psychotropic / Narcotic sections.**
iv. **Authorized Chairman Registration Board for disposal of all types of cases where approval/ recommendation of Registration Board is required for procurement of controlled drug substances/ innovator's drug product pack/ reference and impurity standards etc. for trial/ development & stability purposes.**

Case No.10. Request for Change in Registration Status of Products from M/s Novartis Pharma (Pakistan) Limited, Karachi (DML No.000193) to M/s. AGP Limited, D-109, S.I.T.E, Karachi (DML No. 000044) by way of Contract Manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML No. 000348)

M/s. AGP Limited, D-109, S.I.T.E, Karachi (DML No. 000044) has requested for change in registration status of below mentioned products from M/s Novartis Pharma (Pakistan) Limited, 15-West Wharf, Dockyard Road, Karachi (DML No.000193) to their name by way of contract manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348). **The products were registered dated 13-02-2022 by way of contract manufacturing at M/s GSK Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro (DML No.000010) for a period of 30months.**

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of registration letter and last renewal status.
ii. Copy of DML of M/s AGP Limited, D-109, S.I.T.E, Karachi (Applicant) renewed w.e.f. 15-07-2019
iii. Copy of DML of M/s AGP Limited, B-23-C, S.I.T.E, Karachi (Manufacturer) renewed w.e.f. 06-02-2020
iv. Copy of approved sections by Central Licensing Board of M/s AGP Limited, D-109, S.I.T.E, Karachi showing 3 sections (Tablet Cephalosporin, Capsule Cephalosporin, Dry Syrup Cephalosporin)
v. Copy of approved sections by Central Licensing Board of M/s AGP Limited, B-23-C, S.I.T.E, Karachi, confirming "Tablet (general)" section (Reference letter dated 30-06-2020)
vi. Copy of GMP certificate M/s AGP Limited, D-109, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)
vii. Copy of last GMP Inspection report dated 06-07-2022 concluding good level of GMP compliance by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348)

viii.	NOC from Novartis Pharma (Pakistan) Limited, Karachi in the name of M/s AGP Limited, D-109, S.I.T.E, Karachi issued on 23-06-2022
ix.	Contract Agreement between M/s AGP Limited, D-109, S.I.T.E and M/s AGP Limited, B-23-C, S.I.T.E dated 02-05-2022.
x.	Application with Form-5F and required fee as per relevant SRO.
xi.	Relevant undertakings & commitments.

The cases were referred to QMS for scrutinization/evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Evaluator: Mst. Urooj Fatima (AD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	018615	Axcin 250mg Tablets Each tablet contains: - Ciprofloxacin HCl eq. to Ciprofloxacin……250mg (USP Specifications)	Initial Reg. Date: **23-01-1996** Grant of registration in name of M/s Novartis Pharma (Pakistan) Limited, Karachi on contract manufacturing basis from M/s GSK Consumer Healthcare, Jamshoro, for the period of 30 months: **13-02-2020** Last Renewal applied: **28-01-2021** Change of FPS: **09-05-2022**
	Name, address of Applicant / Marketing Authorization Holder		**M/s. AGP Limited, D-109, S.I.T.E, Karachi DML # 000044**
	Name, address of Manufacturing site.		M/s AGP Limited, B-23-C, S.I.T.E, Karachi **(DML# 000348)**
	Status of the applicant		☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** Copy of GMP certificate M/s AGP Limited, B-23-C, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)
	Evidence of approval of manufacturing facility		Applicant has provided copy of letter of renewal of DML of manufacturer mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission		Dy.No.20668 (R&I) dated 21-07-2022
	Details of fee submitted		**For transfer of registration:** PKR. 75,000/- DS# 29520769319 dated 07-07-2022

	The proposed proprietary name / brand name	**Axcin 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin Hydrochloride Monohydrate USP eq. to Ciprofloxacin……250mg
	Pharmaceutical form of applied drug	White to off-white coloured, round film coated biconvex shaped, with beveled edges.
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Cipro 250mg Tablet, Bayer Healthcare Pharmaceuticals Inc (FDA)
	For generic drugs (me-too status)	Novidat 250mg Tablet, Sami Pharmaceuticals (Pvt) Ltd. (Reg#011836)
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China.
	1.5.11-Proposed Label	**Not Submitted**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Ciprofloxacin Hydrochloride, related structure, solubilities, and other general properties, manufacturing site, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, refence standard, container closure and stability studies summaries of Ciprofloxacin Hydrochloride. Similarly, information summaries for drug product (Axcin) including its description, composition, pharmaceutical development, pharmaceutical equivalence against Ciproxin, Bayer Pakistan, comparative dissolution profile, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis, impurities,

		specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and test methods for packing materials, and stability studies with study protocol.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 60 months.** DS was packed in a double layered LDPE bag and packaged again in cardboard drums. The DS remained within specified limits as tested on defined intervals.
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Ciproxin 250mg Tablet of M/s Bayer Pakistan Ltd. which shows comparable results within specified limits. The comparative dissolution profile was performed for Axcin 250mg Tablet against the Ciproxin 250mg, manufactured by Bayer Pakistan. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 45mins. Calculation of value is as under:

Sr	Mediums	Time interval	Axcin Tab	Ciproxin Tab
i.	Acidic buffer (pH 1.2)	10 min	87.1%	81.2%
		15 min	94%	90%
		30 min	97.4%	99.2%
		45 min	98.5%	101.7%
ii	Acetate buffer (pH 4.5)	10 min	81.4%	88.2%
		15 min	93.3%	99.5%
		30 min	97.2%	101%
		45 min	98.4%	100.8%
iii	Phosphate Buffer (pH 6.8)	10 min	38.8%	40.6%
		15 min	42.3%	44.4%
		30 min	43.4%	45.9%
		45 min	44.1%	45.4%

		f1 and f2 value has not been calculated for pH 1.2 and 4.5 because both reference and test sample achieved 85% dissolution within 15 minutes. For pH 6.8 F2 has been calculated which is 82.6. On the basis of similarity factor results (not less than 50) both reference and test products are found similar.
	Analytical method validation/verification of product	Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided**. Analytical methods verification was performed in February, 2022.** Dissolution method verification protocol and study report were also provided.

STABILITY STUDY DATA

Manufacturer of API	Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China.		
API Lot No.	DK15-2102093-b		
Description of Pack (Container closure system)	Alu/PVC blister of 1x10's in secondary carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) (Continued for 24 months) Real Time: 0, 3, 6, (Months)		
Batch No.	21/045-STB/CIP-TAB/01	21/046-STB/CIP-TAB/02	21/047-STB/CIP-TAB/03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	03-11-2021	03-11-2021	03-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Quvasc Tablet 10mg, 5mg and 2.5mg of M/s AGP, B-23, S.I.T.E. Karachi Approved in 317th meeting of RB held on 16th & 17th May, 2022
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (Certificate No. ZJ20190157) issued by National Medical Products Administration China, dated 30-11-2019. (Valid up to 29-11-2024).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from M/s Sunmore Healthcare Co. Ltd, Hunan, China (manufactured by

		Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China verified through COA and GMP certificate of manufacturer). invoice dated 02-08-2021, cleared 16-08-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

The drug substance for Axcin 250mg Tablet (Ciprofloxacin HCl) is manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China. (GMP certified by National Medical Products Administration China, on USP specifications. The impurity profiling of DS is also carried out particularly for "Ciprofloxacin diethylamine". Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to USP specifications.

The drug product is film coated tablet of 250mg manufactured by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) (Formulation) (White to off-white coloured, round film coated biconvex shaped, with beveled edges). The method of manufacturing is granulation, direct compression and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

Analytical methods verification was performed in February, 2022, whereas product is manufactured and tested in November, 2021. However, testing was performed as per USP specifications.

M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) is a GMP complaint unit as per certificate issued by DRAP, Karachi office based on inspection conducted on 03-06-2021. (Validity 02 years).

Axcin 250mg Tablets' pharmaceutical equivalence has been established against the Ciproxin 250mg Tablet of M/s Bayer Pakistan Ltd. which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Ciproxin 250mg Tablet of M/s Bayer Pakistan Ltd. The clinical particulars and pharmacological properties of the Ciprofloxacin, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for Skin and Skin Structure Infections, Bone and Joint Infections, Complicated Intra-Abdominal Infections, Infectious Diarrhea, Typhoid Fever (Enteric Fever), Uncomplicated Cervical and Urethral Gonorrhea, Inhalational Anthrax post-exposure in adult and pediatric patients, Lower Respiratory Tract Infections, Urinary Tract Infections, Acute Sinusitis.

Conclusion:

The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.

The firm shall also ensure black boxed information on "Serious Adverse Reactions Including Tendinitis, Tendon Rupture, Peripheral Neuropathy, Central Nervous System Effects and Exacerbation of Myasthenia Gravis" in the beginning of the leaflet.			
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
2.	018616	Axcin 500mg Tablets Each tablet contains: - Ciprofloxacin HCl eq. to Ciprofloxacin……500mg (USP Specifications)	Initial Reg. Date: **23-01-1996** Grant of registration in name of M/s Novartis Pharma (Pakistan) Limited, Karachi on contract manufacturing basis from M/s GSK Consumer Healthcare, Jamshoro, for the period of 30 months: **13-02-2020** Last Renewal applied: **28-01-2021** Change of FPS: **09-05-2022**
	Name, address of Applicant / Marketing Authorization Holder		**M/s. AGP Limited, D-109, S.I.T.E, Karachi DML # 000044**
	Name, address of Manufacturing site.		M/s AGP Limited, B-23-C, S.I.T.E, Karachi **(DML# 000348)**
	Status of the applicant		☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** Copy of GMP certificate M/s AGP Limited, B-23-C, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)
	Evidence of approval of manufacturing facility		Applicant has provided copy of letter of renewal of DML of manufacturer mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission		Dy.No.20669 (R&I) dated 21-07-2022
	Details of fee submitted		**For transfer of registration:** PKR. 75,000/- DS# 398056408611 dated 07-07-2022
	The proposed proprietary name / brand name		**Axcin 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film coated tablet contains: Ciprofloxacin Hydrochloride Monohydrate USP eq. to Ciprofloxacin……500mg

	Pharmaceutical form of applied drug	White to off-white coloured, round film coated biconvex shaped, with beveled edges.
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Cipro 500mg Tablet, Bayer Healthcare Pharmaceuticals Inc (FDA)
	For generic drugs (me-too status)	Novidat 500mg Tablet, Sami Pharmaceuticals (Pvt) Ltd. (Reg#011837)
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China.
	1.5.11-Proposed Label	**Not Submitted**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Ciprofloxacin Hydrochloride, related structure, solubilities, and other general properties, manufacturing site, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, refence standard, container closure and stability studies summaries of Ciprofloxacin Hydrochloride. Similarly, information summaries for drug product (Axcin) including its description, composition, pharmaceutical development, pharmaceutical equivalence against Ciproxin, Bayer Pakistan, comparative dissolution profile, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis, impurities, specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and test methods for packing materials, and stability studies with study protocol.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches

	(Conditions & duration of Stability studies)	of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 60 months.** DS was packed in a double layered LDPE bag and packaged again in cardboard drums. The DS remained within specified limits as tested on defined intervals.
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Ciproxin 500mg Tablet of M/s Bayer Pakistan Ltd. which shows comparable results within specified limits. The comparative dissolution profile was performed for Axcin 500mg Tablet against the Ciproxin 500mg, manufactured by Bayer Pakistan. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 45mins. Calculation of value is as under:

Sr	Mediums	Time interval	Axcin Tab	Ciproxin Tab
i.	Acidic buffer (pH 1.2)	10 min	59.6%	66.8%
		15 min	92%	91%
		30 min	93.1%	96.3%
		45 min	94.8%	98%
ii	Acetate buffer (pH 4.5)	10 min	85.1%	78.5%
		15 min	96.6%	93%
		30 min	96.9%	98.2%
		45 min	97.5%	99.6%
iii	Phosphate Buffer (pH 6.8)	10 min	2.9%	10.2%
		15 min	3.1%	11.9%
		30 min	3.2%	11.9%
		45 min	4%	11.8%

f1 and f2 value has not been calculated for pH 1.2 and 4.5 because both reference and test sample achieved 85% dissolution within 15 minutes. For pH 6.8 F2 has been calculated which is 54.2. On the basis of similarity factor results (not less than 50)

		both reference and test products are found similar.
	Analytical method validation/verification of product	Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided**. Analytical methods verification was performed in February, 2022.** Dissolution method verification protocol and study report were also provided.

STABILITY STUDY DATA			
Manufacturer of API	Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China.		
API Lot No.	DK15-2102093-b		
Description of Pack (Container closure system)	Alu/PVC blister of 1x10's in secondary carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) (Continued for 24 months) Real Time: 0, 3, 6, (Months)		
Batch No.	21/070-STB/CIP-TAB/01	21/071-STB/CIP-TAB/02	21/072-STB/CIP-TAB/03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	16-12-2021	16-12-2021	16-12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Quvasc Tablet 10mg, 5mg and 2.5mg of M/s AGP, B-23, S.I.T.E. Karachi Approved in 317th meeting of RB held on 16th & 17th May, 2022
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (Certificate No. ZJ20190157) issued by National Medical Products Administration China, dated 30-11-2019. (Valid up to 29-11-2024).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from M/s Sunmore Healthcare Co. Ltd, Hunan, China (manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China, verified through COA and GMP certificate of manufacturer). invoice dated 02-08-2021, cleared 16-08-2021 from DRAP, Karachi.

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

Remarks of Evaluator:

The drug substance for Axcin 500mg Tablet (Ciprofloxacin HCl) is manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China. (GMP certified by National Medical Products Administration China, on USP specifications. The impurity profiling of DS is also carried out particularly for "Ciprofloxacin diethylamine". Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to USP specifications.

The drug product is film coated tablet of 500mg manufactured by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) (Formulation) (White to off-white coloured, round film coated biconvex shaped, with beveled edges). The method of manufacturing is granulation, direct compression and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

Analytical methods verification was performed in February, 2022, whereas product is manufactured and tested in November, 2021. However, testing was performed as per USP specifications.

M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) is a GMP complaint unit as per certificate issued by DRAP, Karachi office based on inspection conducted on 03-06-2021. (Validity 02 years).

Axcin 500mg Tablets' pharmaceutical equivalence has been established against the Ciproxin 250mg Tablet of M/s Bayer Pakistan Ltd. which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Ciproxin 500mg Tablet of M/s Bayer Pakistan Ltd. The clinical particulars and pharmacological properties of the Ciprofloxacin, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for Skin and Skin Structure Infections, Bone and Joint Infections, Complicated Intra-Abdominal Infections, Infectious Diarrhea, Typhoid Fever (Enteric Fever), Uncomplicated Cervical and Urethral Gonorrhea, Inhalational Anthrax post-exposure in adult and pediatric patients, Lower Respiratory Tract Infections, Urinary Tract Infections, Acute Sinusitis.

Conclusion:
The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.
The firm shall also ensure black boxed information on "Serious Adverse Reactions Including Tendinitis, Tendon Rupture, Peripheral Neuropathy, Central Nervous System Effects and Exacerbation of Myasthenia Gravis" in the beginning of the leaflet.

Decision: Registration Board decided as under:

i. **Cancelled registration of following products from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).**

S. No.	Reg. No.	Product Name & Composition
1.	018615	Axcin 250mg Tablets Each tablet contains: - Ciprofloxacin HCl eq. to Ciprofloxacin……250mg (USP Specifications)
2.	018616	Axcin 500mg Tablets Each tablet contains: - Ciprofloxacin HCl eq. to Ciprofloxacin……500mg (USP Specifications)

ii. **Approved registration of following products in the name of M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) by way of contract manufacturing at M/s AGP Limited B-23-C, S.I.T.E. Karachi (DML No. 000348).**
   a) **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
   b) **Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.**

S. No.	Product Name & Composition
1.	Axcin 250mg Tablets Each film coated tablet contains: Ciprofloxacin Hydrochloride Monohydrate USP Eq. to Ciprofloxacin……..…250mg (USP Specifications)
2.	Axcin 500mg Tablets Each film coated tablet contains: Ciprofloxacin Hydrochloride Monohydrate USP Eq. to Ciprofloxacin……..…500mg (USP Specifications)

iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.**

iv. **Legal opinion will be sought from Legal Affairs Division, DRAP whether cases regarding cancellation of registration from one registration holder and issuance of the same in favor of other registration holder on contract manufacturing basis require fee Rs.75000/- or Rs.75000/-+30000/- and registration letter will be issued accordingly.**

Case No. 11: Approved Products of M/s Mediate Pharmaceutical (Pvt) Ltd. Karachi

Registration Board in its 235th meeting (held on 18-09-2012) approved the following products of M/s Mediate Pharmaceutical (Pvt) Ltd. Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi as per details mentioned vide column II & III of below table. The firm has now requested for issuance of registration & submitted requisite fee along-with required documents/ information as per detail recorded vide Column IV of below table:

S/ N	Product Name & Composition	Decision of RB-235	Current Status/ Documents Submitted by the Firm	RRA & Generic Status/ Remarks
I	II	III	IV	V
1.	Madifenac Plus Tablet Each tablet contains:- Diclofenac Sodium .50mg Misoprostol ……200mcg (Anti rheumatics) <u>Demanded MRP/Pack:</u> Rs.200/20's	Approved subject product inspection for bi-layer tablet facility	• Dy.No.11520/R&I dated 12-05-2022 • Differential registration fee of Rs.22000/-(DS#78867109 dated 09-05-2022) • Pre-registration variation fee of Rs.30000/- (DS#6026849524 dated 09-05-2022) for correction in composition as per RRA. Correct composition is: *Each film coated delayed release tablet contains:* *Diclofenac Sodium (Gastro-Resistant Core).....50mg* *Misoprostol (Immediate Release Outer Mantle).....200mcg* • Correct form-5, Master formulation & manufacturing method. • FPP Specifications; USP. • IQ, OQ & PQ report along-with invoice of ZP-420-28D Double Rotary Compression Machine. • Last Inspection Report 17-12-2021.(Acceptable Level of Compliance) • Renewal of DML issued vide Licensing Division's letter dated 15-09-2021 stating approval of "Tablet (General) Section"	• USFDA Approved (with boxed warning) • Osteotec Tablet by M/s CCL, Lahore.
2.	Madifenac Forte Tablet Each tablet contains:-	Approved subject product inspection for bi-	• Dy.No.11522/R&I dated 12-05-2022 • Differential registration fee of Rs.22000/-(DS#6026414777 dated 09-05-2022)	• USFDA Approved

	Diclofenac Sodium……..…75 mg Misoprostol ….200mcg (Anti rheumatics) <u>Demanded MRP/Pack:</u> Rs.300/20's	layer tablet facility	• Pre-registration variation fee of Rs.30000/- (DS#978201833802 dated 09-05-2022) for correction in composition as per RRA. Correct composition is: *Each film coated delayed release tablet contains:* *Diclofenac Sodium (Gastro-Resistant Core).....75mg* *Misoprostol (Immediate Release Outer Mantle).....200mcg* • Correct form-5, Master formulation & manufacturing method. • FPP Specifications; USP. • IQ, OQ & PQ report along-with invoice of ZP-420-28D Double Rotary Compression Machine. • Last Inspection Report 17-12-2021.(Acceptable Level of Compliance) • Renewal of DML issued vide Licensing Division's letter dated 15-09-2021 stating approval of "Tablet (General) Section"	(with boxed warning) • Osteotec Tablet by M/s CCL, Lahore.

Decision: Registration Board approved registration of products at S. No. 1-2 of above table in the name of M/s Mediate Pharmaceutical (Pvt) Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi.

Case No.12. Request for Change in Registration Status of Kapdex Capsules from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi (DML No. 000012) to M/s Aspin Pharma Pvt Ltd., Korangi Industrial Area Karachi (DML No. 000045), through contract manufacturing.

M/s. Aspin Pharma (Pvt.) Ltd., Plot No.10 & 25 Sector 20, Korangi (DML No.000045) Industrial Area Karachi has requested to change the product registration status of Kapdex 60mg and 30mg Capsules from M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi (DML No.000012) to their name. However, the product will continue to be manufactured at the manufacturing site of M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan Pvt Ltd.) C-14, S.I.T.E, Karachi through contract manufacturing.

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan Ltd.) on the basis of inspection conducted on 08-10-2021.
ii. Copy of DML of M/s OBS Pakistan Pvt Ltd., (DML # 000012) renewed w.e.f. 26-10-2020 and M/s Aspin Pharma Pvt Ltd, (DML# 000045) renewed w.e.f 31-03-2020..

iii. Copy of panel inspection report of M/s Searle Pakistan for GMP Certification dated 08-10-2021 confirming "Capsule (General) Section on the GMP Certification" Copy of DRAP's letter dated 16th June, 2021 for renewal of DML of M/s Aspin Pharma Pvt Ltd, mentioning Capsule General among sections
iv. NOC from M/s. The Searle Company Ltd; Karachi for transfer of Kapdex 60mg and 30mg Capsules in the name of M/s. Aspin Pharma Pvt Pharma Pvt Ltd., Korangi Industrial Area, Karachi issued on 31-10-2022
v. Relevant undertakings & commitments.
vi. Contract Agreement between M/s Aspin Pharma Pvt Ltd, and M/s OBS Pharma.

The cases were referred to Pharmaceutical Evaluation Cell / QMS for scrutinization/evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Evaluator: Mr. Asadullah (AD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	089148	Kapdex 60mg Capsule Each capsule contains: - Dexlansoprazole dual delayed release pellets eq. to Dexlansoprazole 60mg (As per Innovator's Specification)	**Initial Reg. Date: 31-05-2018**
	089147	Kapdex 30mg Capsule Each capsule contains: - Dexlansoprazole dual delayed release pellets eq. to Dexlansoprazole 30mg (As per Innovator's Specification)	
	Name, address of Applicant / Marketing Authorization Holder		**M/s** Aspin Pharma Pvt Pharma Pvt Ltd. **Address: Plots # 10 & 25, Sector 20 Korangi Industrial Area Karachi – 74900, Pakistan**
	Name, address of Manufacturing site.		M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)
	Status of the applicant		☐Manufacturer ☐Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan (Pvt Ltd, C-14, Manghopir Road, S.I.T.E , Karachi- 75700, issued on 15-02-2022 based on inspection conducted on 08.10.2021.

	Evidence of approval of manufacturing facility	Applicant has provided copies of letter dated 13th April, 2018 and GMP certificate of dated 31st Jan, 2020 showing Capsule (General) among Formulation sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21096: 26-06-2022
	Details of fee submitted	**For transfer of registration and contract manufacturing** PKR 150,000/-, DS 158578340 dated 18-02-22 PKR.75,000/-:DS 33846087281 dated 01-11-22
	The proposed proprietary name / brand name	**Kapdex 60 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: 270mg Dexlansoprazole Dual Release Pellets 22.5% w/w, equivalent to 60mg of Dexlansoprazole
	Pharmaceutical form of applied drug	HPMC capsule size # 1, green opaque cap and white opaque body containing white to off white enteric coated pellets.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3 x 10's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Dexilant 60mg Capsule, Takeda Pharmaceuticals America,
	For generic drugs (me-too status)	Razodex 60mg Capsule(Dexlansoprazole, Getz Pharma (Pvt.) Ltd, Karachi (Reg# 086977)
	Name and address of API manufacturer.	M/s Alphamed Formulations Pvt Ltd, Sy.No. 225, sampanbole village, shamirpet Mandal, Medchal Malkajgiri, District Talengana, India
	1.5.11-Proposed Label	Submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Pellets of Dexlansoprazole were formulated at manufacturing site of M/s Alphamed, India, who has provided information summaries related to structure, properties, solubility, ingredients,

		manufacturing process and in-process controls. Dexlansoprazole pellets were formulated by two types of enteric coating of granules with different polymers intended to exhibit dual release in small intestines. The excipients used in pellets manufacturing were in- compliance to compendial and accordingly analytical methods used to test were pharmacopial. Four critical steps of manufacturing were controlled using four types of in-process test. Manufacturer's In-house analytical method was developed and validated for analysis including identification, assay, dissolution, sugar test, related substances, water contents, and size of Dexlansoprazole pellets. Working standard characterized against USP reference standard was used by M/s Alphamed. A Stability of pellets was conducted for long term and real time duration at zone iv (a) conditions. Applicant M/s OBS Pharma provided summaries of information related to description of finished dosage (Capsules), composition of each capsule, critical steps for encapsulation process, batch formula, in-house developed specifications, analytical procedure and its validation, CoA of raw DS, batch analysis, working standard, container closure system and stability studies of drug product. Information summaries for analytical method procedures and validation were provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubility, physical form, DS and raw material specifications, manufacturers, quantitative composition of dexlansoprazole pellets, manufacturing process, excipients specifications, CoAs and Standard testing procedures. Dexlansoprazole identification and character elucidations was provided M/s Nifty Labs, Pvt Ltd. Analytical methods was developed by M/s Alphamed, India and its validation studies was performed and accordingly an in-house specification was developed. Analytical methods and CoA of excipients were provided. Impurity profiling was established for process impurities, and residual solvents. Certificate of analysis of working standard Lansoprazole was provided. Container closure system of pellets comprises on LPDE bags, triple layered

		aluminium bags in HDPE Drums, and Packaging material specifications were provided. Three batches were subjected to stability studies and based on the data 36month shelf life is proposed for pellets.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches (60 kg each, Mfg Date: 12-2015 & May-2016) of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^oC \pm 2^oC$ / 75% ± 5% RH for 6 months and the real time stability data is conducted at $30^oC \pm 2^oC$ / 65% ± 5% RH for 36 months. The spherical dexlansoprazole Pellets were placed in a single layered aluminium bag and single layered LDPE bag in a HDPE Container. Pellets exhibit stability upto entire period of stability.
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, formulation, encapsulation method, manufacturing procedure, critical parameters of manufacturing process, pharmaceutical development, manufacture, manufacturing process, process control and , control of excipients, specifications, analytical procedures and its validation, batch analysis, justification of specifications, analytical procedure for impurities as per DS method, working standard, container closure system and stability. Analytical method was developed based on the method defined by Alphamed, India and accordingly product specifications has been defined.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The comparative dissolution profile was performed against the Dexilent 60mg Capsule, manufactured by Takeda Pharmaceuticals, America. Comparison was performed in three dissolution medium at pH 1.2, pH 5.5 and pH 7.0 using 12 samples at 10, 20,30, 40, 50, 60 and 120 minutes. Calculation of value was f1 and f2 were in compliance.
	Analytical method validation/verification of product	Firm has provided validation of analytical method protocol and report for both pellets and finished drug product. Firm has also provided validation of dissolution method. The product specification reflects dissolution profiling at both acidic stage, and four steps dissolution at pH 7.0 to monitor dual release pattern.

STABILITY STUDY DATA			
Manufacturer of API	M/s Alphamed Formulations Pvt Ltd, Sy.No. 225, sampanbole village, shamirpet Mandal, Medchal Malkajgiri, District Talengana, India		
API Lot No.	AJ4A0002/B		
Description of Pack (Container closure system)	Alu/PVC blister in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months (**data submitted for 06 month**) Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,24 (Months)		
Batch No.	027DT01	027DT012	027DT03
Batch Size	3000 Capsules	3000 Capsules	3000 Capsules
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	11-05-2020	11-05-2020	11-05-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	M/s Searle Pakistan Ltd (Formerly M/s OBS Pakistan Ltd) has approved Dextop (Dexlansoprazole 60mg Capsule).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued of M/s Alphamed Formulation Pvt Ltd, issued by the Drug Control Administration, Government of Telangana, India. Issued on 30-08-2019 with 03 years validity. This certificate mentioned Dexlansoprazole in approved products list.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 4.5 Kg Dexlansoprazole pellets dated 11-02-2019, cleared from DRAP Karachi office dated 18-Mar-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.
2	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma Pvt Pharma Pvt Ltd. Address: Plots # 10 & 25, Sector 20 Korangi Industrial Area Karachi – 74900,**

		Pakistan
	Name, address of Manufacturing site.	M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)
	Status of the applicant	☐Manufacturer ☐Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm	**For transfer of registration:** GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan (Pvt Ltd, C-14, Manghopir Road, S.I.T.E , Karachi- 75700, issued on 15-02-2022 based on inspection conducted on 08.10.2021.
	Evidence of approval of manufacturing facility	Applicant has provided copies of letter dated 13th April, 2018 and GMP certificate of dated 31st Jan, 2020 showing Capsule (General) among Formulation sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 21095: 26-06-2021
	Details of fee submitted	**For transfer of registration and contract manufacturing** PKR 150,000/-DS 33846087281 dated 01-11-22 PKR.75,000/- DS 158578340 dated 18-02-22
	The proposed proprietary name / brand name	**Kapdex 30 mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: 135mg Dexlansoprazole Dual Release Pellets 22.5% w/w, equivalent to 30mg of Dexlansoprazole
	Pharmaceutical form of applied drug	HPMC capsule size # 3, blue opaque cap and white opaque body containing white to off white enteric coated pellets.
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3 x 10's
	Proposed unit price	As per DPC

	The status in reference regulatory authorities	Dexilant 30mg Capsule, Takeda Pharmaceuticals America,
	For generic drugs (me-too status)	Razodex 30mg Capsule(Dexlansoprazole, Getz Pharma (Pvt.) Ltd, Karachi (Reg# 086976)
	Name and address of API manufacturer.	M/s Alphamed Formulations Pvt Ltd, Sy.No. 225, sampanbole village, shamirpet Mandal, Medchal Malkajgiri, District Talengana, India
	1.5.11-Proposed Label	Submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Pellets of Dexlansoprazole were formulated at manufacturing site of M/s Alphamed, India, who has provided information summaries related to structure, properties, solubility, ingredients, manufacturing process and in-process controls. Dexlansoprazole pellets were formulated by two types of enteric coating of granules with different polymers intended to exhibit dual release in small intestines. The excipients used in pellets manufacturing were in- compliance to compendial and accordingly analytical methods used to test were pharmacopial. Four critical steps of manufacturing were controlled using four types of in-process test. Manufacturer's In-house analytical method was developed and validated for analysis including identification, assay, dissolution, sugar test, related substances, water contents, and size of Dexlansoprazole pellets. Working standard characterized against USP reference standard was used by M/s Alphamed. A Stability of pellets was conducted for long term and real time duration at zone iv (a) conditions. Applicant M/s OBS Pharma provided summaries of information related to description of finished dosage (Capsules), composition of each capsule, critical steps for encapsulation process, batch formula, in-house developed specifications, analytical procedure and its validation, CoA of raw DS, batch analysis, working standard, container closure system and stability studies of drug product. Information summaries for analytical method procedures and validation were provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general

		properties, solubility, physical form, DS and raw material specifications, manufacturers, quantitative composition of dexlansoprazole pellets, manufacturing process, excipients specifications, CoAs and Standard testing procedures. Dexlansoprazole identification and character elucidations was provided M/s Nifty Labs, Pvt Ltd. Analytical methods was developed by M/s Alphamed, India and its validation studies was performed and accordingly an in-house specification was developed. Analytical methods and CoA of excipients were provided. Impurity profiling was established for process impurities, and residual solvents. Certificate of analysis of working standard Lansoprazole was provided. Container closure system of pellets comprises on LPDE bags, triple layered aluminium bags in HDPE Drums, and Packaging material specifications were provided. Three batches were subjected to stability studies and based on the data 36month shelf life is proposed for pellets.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches (60 kg each, Mfg Date: 12-2015 & May-2016) of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at $40^oC \pm 2^oC$ / 75% ± 5% RH for 6 months and the real time stability data is conducted at $30^oC \pm 2^oC$ / 65% ± 5% RH for 36 months. The spherical dexlansoprazole Pellets were placed in a single layered aluminium bag and single layered LDPE bag in a HDPE Container. Pellets exhibit stability upto entire period of stability.
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, formulation, encapsulation method, manufacturing procedure, critical parameters of manufacturing process, pharmaceutical development, manufacture, manufacturing process, process control and , control of excipients, specifications, analytical procedures and its validation, batch analysis, justification of specifications, analytical procedure for impurities as per DS method, working standard, container closure system and stability. Analytical method was developed based on the method defined by Alphamed, India and accordingly product specifications has been defined.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	The comparative dissolution profile was performed for against the Dexilent 30mg Capsule, manufactured by Takeda Pharmaceuticals, America. Comparison was performed in three dissolution medium at pH 1.2, pH 5.5 and pH 7.0 using 12 samples at 10, 20, 30, 40, 50, 60 and 120 minutes. Calculation of value was f1 and f2 were in compliance.
	Analytical method validation/verification of product	Firm has provided validation of analytical method protocol and report for both pellets and finished drug product. Firm has also provided validation of dissolution method. The product specification reflects dissolution profiling at both acidic stage, and four steps dissolution at pH 7.0 to monitor dual release pattern.

STABILITY STUDY DATA			
Manufacturer of API	M/s Alphamed Formulations Pvt Ltd, Sy.No. 225, sampanbole village, shamirpet Mandal, Medchal Malkajgiri, District Talengana, India		
API Lot No.	AJ4A0002/B		
Description of Pack (Container closure system)	Alu/PVC blister in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months (**data submitted for 06 month**) Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,24 (Months)		
Batch No.	026DT01	026DT012	026DT03
Batch Size	3000 Capsules	3000 Capsules	3000 Capsules
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	11-05-2020	11-05-2020	11-05-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	M/s Searle Pakistan Ltd (Formerly M/s OBS Pakistan Ltd) has approved Dextop (Dexlansoprazole 60mg Capsule).
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued of M/s Alphamed Formulation Pvt Ltd, issued by the Drug Control Administration, Government of Telangana, India. Issued on 30-08-2019 with 03 years validity. This certificate mentioned Dexlansoprazole in approved products list.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying purchase of 4.5 Kg

		Dexlansoprazole pellets dated 11-02-2019.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s OBS Pakistan Pvt. Ltd. (Current Title: M/s Searle Pakistan Limited), C-14, S.I.T.E, Karachi (DML No.000012).

S. No.	Reg. No.	Product Name & Composition
1.	**089148**	**Kapdex 60mg Capsule** **Each capsule contains: -** **Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole……..60mg** **(As per Innovator's Specification)**
2.	**089147**	**Kapdex 30mg Capsule** **Each capsule contains: -** **Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole…….30mg** **(As per Innovator's Specification)**

ii. Approved registration of following products in the name of M/s. Aspin Pharma (Pvt.) Ltd., Plot No.10 & 25 Sector 20, Korangi Industrial Area, Karachi (DML No.000045) by way of contract manufacturing at M/s Searle Pakistan Limited (Formerly M/s OBS Pakistan Pvt. Ltd.) C-14, S.I.T.E, Karachi (DML No.000012).

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

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name & Composition
ii.	**Kapdex 60mg Capsule** **Each capsule contains: -**

	Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole……..…..60mg (As per Innovator's Specifications)
iii.	**Kapdex 30mg Capsule Each capsule contains: - Dexlansoprazole Dual Delayed Release Pellets Eq. to Dexlansoprazole……..….30mg (As per Innovator's Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.

iv. Before issuance of registration letter, the applicant shall submit valid and legalized GMP certificate of M/s Alphamed Formulations Pvt. Ltd., Sy.No. 225, Sampanbole Village, Shamirpet Mandal, Medchal Malkajgiri, District Talengana, India.

Case No.13. Request for Change in Registration Status of Products from M/s The Searle Company Limited Karachi (DML No.000016) to M/s Searle Pakistan Limited (Formerly OBS Pakistan Private Limited Karachi) (DML No.000012).

M/s. Searle Pakistan Limited (Formerly OBS Pakistan Pvt Ltd.), C-14, Manghopir Road, S.I.T.E, Karachi (DML No.000012) has requested for change in registration of below mentioned products from M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016) to their name.

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate on the basis of inspection conducted on 08-10-2021.
ii. Copy of DML (000012) of M/s OBS renewed w.e.f. 31-03-2020.
iii. Copy of renewal of DML issued by Licensing Division vide letter dated 26-10-2020 stating approval of "Tablet (General) Section" among others.
iv. NOC from M/s. The Searle Company Ltd; Karachi for transfer of Olesta 40mg and 20mg Tablet in the name of M/s. Searle Pakistan Limited (Formerly OBS Pakistan Pvt Ltd.), C-14, Manghopir Road, S.I.T.E, Karachi issued on 04-11-2022
v. Relevant undertakings & commitments.

The cases were referred to Pharmaceutical Evaluation Cell / QMS for scrutinization/evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Evaluator: Mr. Asadullah (AD-QMS)

I	**II**	**III**	**IV**
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	050737	Olesta 40mg Tablets	Initial Reg. Date: 24-09-2008 Change of Name / Title of Reg. Holder: 19-08-

		Each tablet contains: - Olmesartan Medoxomil…..…40mg (Manufacturer's Specification)	2016 Last Renewal Submission Date: 01-07-2021 Remarks of RRR Section: Renewal is within time w.r.t. registration to new title.
	Name, address of Applicant / Marketing Authorization Holder		**M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700,,Sindh, Pakistan**
	Name, address of Manufacturing site.		M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan (Pvt Ltd, C-14, Manghopir Road, S.I.T.E , Karachi- 75700, issued on 15-02-2022 based on inspection conducted on 08.10.2021.
	Evidence of approval of manufacturing facility		Applicant has provided copy of letter dated 26-10-2020 of renewal of DML mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission		Dy.No.8545 (R&I) dated 01-04-2022 Dy.No 579 AD(Reg-I) dated 04-04-2022
	Details of fee submitted		**For transfer of registration:** PKR (20,000/- + 10,000) = 30,000/- DS# 45853132641 dated 10-04-2021 DS# 18372243 dated 08-11-02-2021
	The proposed proprietary name / brand name		**Olesta 40 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film coated tablet contains: Olmesartan Medoxomil 40mg

	Pharmaceutical form of applied drug	Off-white round concave shaped, film coated tablet with break line on one side and plain from other side.
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker, Anti-hypertensive
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	14's and 10's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Olmetec 40mg Tablet, Daiichi Sankyo ilac Tic., Ltd, Turkey, (MHRA Approved)
	For generic drugs (me-too status)	Baritec 40mg Tablet, Barret Hodgson Pakistan (Pvt) Ltd. (Reg#058039)
	Name and address of API manufacturer.	Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund, Pune, Zone-4, India
	1.5.11-Proposed Label	Submitted
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Olmesartan medoxomil (DS) physical properties, solubilities, polymorphism, other general properties, manufacturing site, Characterization elucidation using FTIR, impurities profiling of organic / in-process known impurities as per USP monograph and analysis of 03 batches data (NMT 0.10% and total impurities NMT 1.30%), other impurities like heavy metals and residual solvents were also controlled in DS specifications. USP based DS specifications were followed by DP manufacturer. Analytical procedures for DS were verified against USP methods by DP manufacturer. DS lot procured is analyzed. Working standards, container closure and stability studies summaries of 03 batches of Olmesartan medoxomil was provided under Zone IV-b. Similarly, information summaries for drug product (Olesta) including its description, composition, choice of excipients, pharmaceutical development, pharmaceutical equivalence against Benicar, Daiichi Turkey, comparative dissolution profile, justification for selection of manufacturing process and in-process controls, DP specification based on USP, excipients control, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process,

<table>
<tr><td></td><td></td><td>polymorphism (no isomerism), structure elucidation using UV, FTIR, NMR, etc. Impurities , heavy metals and residual solvents were also identified and analysed in 03 DS batches, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis of DS lot, impurities, specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA container closure system, specification and test methods for packing materials, and stability studies with study protocol.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 36 months. DS was packed in a double polyethylene bag (inner clear and outer black opaque) and placed in a fibre board / HDPE Drum. The DS remained within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Olmetec 40mg Tablet which shows comparable results within specified limits.
The comparative dissolution profile was performed for Olesta 40mg Tablet against the Olmetec 40mg, manufactured by Daiichi sankyo, Turkey. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 20min. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Olesta 40mg Tab</th><th>Olmetec 40mg Tab</th></tr>
<tr><td rowspan="4">i.</td><td rowspan="4">Acidic buffer (pH 1.2)</td><td>10 min</td><td>103 %</td><td>103 %</td></tr>
<tr><td>15 min</td><td>100 %</td><td>98 %</td></tr>
<tr><td>20 min</td><td>100 %</td><td>97 %</td></tr>
<tr><td colspan="3">f1 = 1
f2= 85</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td rowspan="6">ii</td><td rowspan="6">Acetate buffer (pH 4.5)*</td><td>10 min</td><td>09 %</td><td>10 %</td></tr>
<tr><td>15 min</td><td>10 %</td><td>10 %</td></tr>
<tr><td>20 min</td><td>11 %</td><td>11 %</td></tr>
<tr><td>25 min</td><td>12 %</td><td>11 %</td></tr>
<tr><td>30 min</td><td>12 %</td><td>11 %</td></tr>
<tr><td colspan="3">f1=4
f2=96</td></tr>
<tr><td rowspan="6">iii</td><td rowspan="6">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>52 %</td><td>64 %</td></tr>
<tr><td>15 min</td><td>64 %</td><td>70 %</td></tr>
<tr><td>20 min</td><td>70 %</td><td>75 %</td></tr>
<tr><td>25 min</td><td>76 %</td><td>80 %</td></tr>
<tr><td>30 min</td><td>82 %</td><td>83 %</td></tr>
<tr><td colspan="3">f1=8
f2=59</td></tr>
</table>
* The solubility of Olmesartan is pH dependent, and it is practically insoluble at pH 4.0.
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided. Dissolution method verification protocol and study report were also provided which meets the acceptance criteria for verification.</td></tr>
</table>

<table>
<tr><th colspan="5">STABILITY STUDY DATA</th></tr>
<tr><td>Manufacturer of API</td><td colspan="4">Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund, Pune, Zone-4, India</td></tr>
<tr><td>API Lot No.</td><td colspan="4">83191080</td></tr>
<tr><td>Description of Pack (Container closure system)</td><td colspan="4">Alu/PVC blister in unit carton</td></tr>
<tr><td>Stability Storage Condition</td><td colspan="4">Real time: 30˚C ± 2˚C / 75% ± 5%RH
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH</td></tr>
<tr><td>Time Period</td><td colspan="4">Real time: 12 months (Continue for 36 months)
Accelerated: 6 months</td></tr>
<tr><td>Frequency</td><td colspan="4">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 12 (Months)</td></tr>
<tr><td>Batch No.</td><td>022DT01</td><td>022DT02</td><td colspan="2">022DT03</td></tr>
<tr><td>Batch Size</td><td>3000 Tablets</td><td>3000 Tablets</td><td colspan="2">3000 Tablets</td></tr>
<tr><td>Manufacturing Date</td><td>03-2020</td><td>03-2020</td><td colspan="2">03-2020</td></tr>
<tr><td>Date of Initiation</td><td>04-2020</td><td>04-2020</td><td colspan="2">04-2020</td></tr>
<tr><td>No. of Batches</td><td colspan="4">03</td></tr>
<tr><th colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</th></tr>
<tr><td>1.</td><td colspan="2">Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="2">-</td></tr>
</table>

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Administration (Maharashtra State) Pune, India , dated 25-01-2022. (Valid up to 24-01-2023).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from Glenmark Life Sciences, Pune, India, invoice dated 31-12-2019, cleared 27-01-2020 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
2.	050736	Olesta 20mg Tablets Each tablet contains: - Olmesartan Medoxomil…..…20mg (Manufacturer's Specification)	Initial Reg. Date: 24-09-2008 Change of Name / Title of Reg. Holder: 19-08-2016 Last Renewal Submission Date: 01-07-2021 Remarks of RRR Section: Renewal is within time w.r.t. registration to new title.
	Name, address of Applicant / Marketing Authorization Holder		**M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700,,Sindh, Pakistan**
	Name, address of Manufacturing site.		M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) Address: C-14, Manghopir Road, S.I.T.E , Karachi- 75700, Sindh, Pakistan. **(DML 000012)** (change of Name / Title of DML holder by CLB in 283rd meeting letter date 23-11-2021)
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** GMP certificate of M/s Searle Pakistan Ltd (Formerly OBS Pakistan (Pvt Ltd, C-14, Manghopir Road, S.I.T.E , Karachi- 75700, issued on 15-02-2022 based on inspection conducted on 08.10.2021.

	Evidence of approval of manufacturing facility	Applicant has provided copy of letter dated 26-10-2020 of renewal of DML mentioning Tablet (General) section among Formulation sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No.8544 (R&I) dated 01-04-2022 Dy.No 310 AD(Reg-I) dated 05-04-2022
	Details of fee submitted	**For transfer of registration:** PKR (20,000/- + 10,000) = 30,000/- DS# 9748231907 dated 12-04-2021 DS# 794533744497 dated 08-11-02-2021
	The proposed proprietary name / brand name	**Olesta 20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Olmesartan Medoxomil 20mg
	Pharmaceutical form of applied drug	White to Off-white round concave shaped, film coated tablet with break line on one side and plain from other side.
	Pharmacotherapeutic Group of (API)	Angiotensin receptor blocker, Anti-hypertensive
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	14's and 10's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Olmetec 20mg Tablet, Daiichi Sankyo ilac Tic., Ltd, Turkey, (MHRA Approved)
	For generic drugs (me-too status)	Baritec 20mg Tablet, Barret Hodgson Pakistan (Pvt) Ltd. (Reg#058038)
	Name and address of API manufacturer.	Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund, Pune, Zone-4, India
	1.5.11-Proposed Label	Submitted
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Olmesartan medoxomil (DS) physical properties, solubilities, polymorphism, other general properties, manufacturing site, Characterization elucidation using FTIR, impurities profiling of organic / in-process known impurities as per USP monograph and analysis of 03 batches data (NMT 0.10% and total impurities NMT 1.30%), other impurities like heavy metals and residual solvents

		were also controlled in DS specifications. USP based DS specifications were followed by DP manufacturer. Analytical procedures for DS were verified against USP methods by DP manufacturer. DS lot procured is analyzed. Working standards, container closure and stability studies summaries of 03 batches of Olmesartan medoxomil was provided under Zone IV-b. Similarly, information summaries for drug product (Olesta) including its description, composition, choice of excipients, pharmaceutical development, pharmaceutical equivalence against Benicar, Daiichi Turkey, comparative dissolution profile, justification for selection of manufacturing process and in-process controls, DP specification based on USP, excipients control, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism (no isomerism), structure elucidation using UV, FTIR, NMR, etc. Impurities , heavy metals and residual solvents were also identified and analysed in 03 DS batches, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis of DS lot, impurities, specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and test methods for packing materials, and stability studies with study protocol.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the **long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 36 months**. DS was packed in a double polyethylene bag (inner clear and outer black opaque) and placed in a fibre board / HDPE Drum. The DS remained within specified limits as tested on defined intervals.
	Module-III Drug Product:	Firm has submitted data of drug product including

<table>
<tr><td></td><td></td><td>its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Olmetec 20mg Tablet which shows comparable results within specified limits.
The comparative dissolution profile was performed for Olesta 20mg Tablet against the Olmetec 20mg, manufactured by Daiichi sankyo, Turkey. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 20min. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Olesta 20mg Tab</th><th>Olmetec 20mg Tab</th></tr>
<tr><td rowspan="5">i.</td><td rowspan="5">Acidic buffer (pH 1.2)</td><td>10 min</td><td>99 %</td><td>102 %</td></tr>
<tr><td>15 min</td><td>101 %</td><td>100 %</td></tr>
<tr><td>20 min</td><td>98 %</td><td>100 %</td></tr>
<tr><td colspan="2">f1 = 1
f2= 85</td></tr>
<tr><td rowspan="7">ii</td><td rowspan="7">Acetate buffer (pH 4.5)</td><td>10 min</td><td>11 %</td><td>11 %</td></tr>
<tr><td>15 min</td><td>14 %</td><td>13 %</td></tr>
<tr><td>20 min</td><td>17 %</td><td>17 %</td></tr>
<tr><td>25 min</td><td>19 %</td><td>19 %</td></tr>
<tr><td>30 min</td><td>21 %</td><td>21 %</td></tr>
<tr><td colspan="2">f1=1
f2=98</td></tr>
<tr><td rowspan="7">iii</td><td rowspan="7">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>71 %</td><td>80 %</td></tr>
<tr><td>15 min</td><td>80 %</td><td>91 %</td></tr>
<tr><td>20 min</td><td>80 %</td><td>92 %</td></tr>
<tr><td>25 min</td><td>83 %</td><td>93 %</td></tr>
<tr><td>30 min</td><td>91 %</td><td>95 %</td></tr>
<tr><td colspan="2">f1=10
f2=51</td></tr>
</table></td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided. Dissolution method verification protocol and study report were also provided which meets the acceptance criteria for verification.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
<tr><td>Manufacturer</td><td colspan="2">Glenmark Life Sciences Limited, A-80, MEDIC, Kurkumbh, Tal, Daund,</td></tr>
</table>

of API	Pune, Zone-4, India		
API Lot No.	83191080		
Description of Pack (Container closure system)	Alu/PVC blister in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months (Continue for 36 months) Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 12 (Months)		
Batch No.	021DT01	021DT02	021DT03
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	03-2020	03-2020	03-2020
Date of Initiation	04-2020	04-2020	04-2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Administration (Maharashtra State) Pune, India , dated 25-01-2022. (Valid up to 24-01-2023).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from Glenmark Life Sciences, Pune, India, invoice dated 31-12-2019, cleared 27-01-2020 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

The drug substance for Olesta 40mg and 20 mg Tablets is Olmesartan medoxomil USP, manufactured by Glenmark Life Sciences, Pune, India, (GMP certified by Food and Drug Administration (Maharashtra State) Pune, India). DS has no polymorphic form. The impurity profiling DS was carried as per USP monograph. Manufacturing controls, structural characterization, analytical methods and stability studies has been submitted. Specification is considered adequate with respect to USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to provided specifications.

The drug product is film coated tablet of Olmesartan Medoxomil manufactured by Searle Pakistan Ltd (Formerly OBS Pakistan (Pvt.) Ltd. Karachi DML 000012 (Formulation). The inactive constituents / excipient used in formulation conform to the requirement of pharmacopeia test specification, except the coating material which conform to in-house specification. The method of manufacturing is granulation, direct compression and film coating with adequate in process controls. Analytical and dissolution methods were verified as per USP monograph and final drug product is packed in an Alu PVC blisters as container closure system. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

M/s Searle Pakistan Limited, (Formerly M/s OBS Pakistan (Pvt.) Ltd.) is a GMP complaint unit as per certificate issued by DRAP, Karachi office based on the inspection conducted on 15-02-2022.

The pharmaceutical equivalence of Olesta tablets has been established against the corresponding strength of Olmetec Tablets approved by the MHRA. The comparative dissolution profile was also studied for both strengths of Olesta against Olmetec tablets. The clinical particulars and pharmacological properties of the Olmesartan medoxomil, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for treatment of essential hypertension in adults.
The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference drug product as approved by reference regulatory authority and this information shall be updated regularly when any new information becomes available for reference drug product in accordance with the post registration variation procedures.
The firm shall also ensure inclusion of warning about the risk of an intestinal condition known as sprue-like enteropathy to the drug's label, in light with the FDA safety communication on Olmesartan medoxomil.

M/s. Searle Pakistan Limited (Formerly OBS Pakistan Pvt Ltd.), C-14, Manghopir Road, S.I.T.E, Karachi (DML No.000012) has requested for change in registration of below mentioned products from M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016) to their name.

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s The Searle Company Ltd., F-319, S.I.T.E Karachi (DML No.000016).

S. No.	Reg. No.	Product Name & Composition
1.	050737	**Olesta 40mg Tablets** **Each tablet contains: -** **Olmesartan Medoxomil……..…40mg** **(Manufacturer's Specification)**
2.	050736	**Olesta 20mg Tablets** **Each tablet contains: -** **Olmesartan Medoxomil……..…20mg**

		(Manufacturer's Specification)

ii. Approved registration of following products in the name of M/s Searle Pakistan Limited (Formerly M/s OBS Pakistan Pvt. Ltd.) C-14, S.I.T.E, Karachi (DML No.000012).

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

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name & Composition
i.	**Olesta 40mg Tablets** **Each film coated tablet contains: -** **Olmesartan Medoxomil……..…40mg** **(USP Specifications)**
ii.	**Olesta 20mg Tablets** **Each film coated tablet contains: -** **Olmesartan Medoxomil……..…20mg** **(USP Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.

Case No.14. Request for Change in Registration Status of Caflam 50mg Tablets from M/s Novartis Pharma Pakistan Limited, 15 West Wharf, Karachi (DML # 000193) to M/s Novartis Pharma Pakistan Limited (Formerly Bayer Pakistan Pvt. Ltd.,), S.I.T.E, Karachi (DML # 000003).

M/s. Novartis Pharma Pakistan Limited has requested to change the registration status of Caflam 50mg Tablet from M/s Novartis Pharma Pakistan Limited, 15- West Wharf, Dockyard Road, Karachi (DML#000193) to M/s Novartis Pharma Pakistan Limited, C-21, S.I.T.E, Area, Karachi (DML#000003). They have also requested for change in the manufacturing site from M/s GSK CHC, Jamshoro (i.e., contact manufacturer) to the M/s Novartis Pharma Pakistan Limited, C-21, S.I.T.E, Area, Karachi (i.e., self-manufacturing).

The detail of case is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate on the basis of inspection conducted on 08-09-2021.
ii. Copy of DML of M/s Novartis Pharma Pakistan Limited (DML # 000003) renewed w.e.f. 18-09-2020.
iii. Copy of Tablet (General) section approval letter dated 28-12-2021 issued by Licensing Division in the name of M/s Novartis Pharma Pakistan Ltd, C-21, S.I.T.E Area Karachi (DML # 000003)

iv. NOC from M/s. Novartis Pharma Pakistan Limited, 15- West Wharf, Dockyard Road, Karachi for transfer of Caflam 50mg Tablet on the name of M/s. Novartis Pharma Pakistan Limited (Formerly M/s Bayer Pakistan (Pvt.) Ltd,), C-21, S.I.T.E, Area, Karachi, issued on 09-09-2022
v. Relevant undertakings & commitments.

The cases were referred to Pharmaceutical Evaluation Cell / QMS for evaluation. Detail of submitted documents and remarks of evaluators have been mentioned as under:

Evaluator: Mr. Asadullah (AD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	021528	Caflam 50mg Tablets Each tablet contains: - Diclofenac Potassium 50mg (Manufacturer's Specification)	Reg. Date: **13-02-2020** **Contract Manufacturing Permission valid for a period of 30 Months.** Last Renewal Submission Date: **21-02-2022 with fee of Rs.75000/-**
	Name, address of Applicant / Marketing Authorization Holder		**M/s. Novartis Pharma (Pakistan) Limited (**Formerly M/s Bayer Pakistan (Pvt.) Ltd**), C-21, S.I.T.E. Area, 75700, Karachi, Pakistan**
	Name, address of Manufacturing site.		M/s. Novartis Pharma (Pakistan) Limited (Formerly M/s Bayer Pakistan (Pvt.) Ltd), C-21, S.I.T.E. Area, 75700, Karachi, Pakistan **(DML 000003)**
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** GMP certificate of M/s. Novartis Pharma (Pakistan) Limited (Formerly M/s Bayer Pakistan (Pvt.) Ltd), C-21, S.I.T.E. Area, 75700, Karachi issued on 31-12-2021 based on inspection conducted on 08.09.2021.
	Evidence of approval of manufacturing facility		Applicant has provided copy of GMP certificate 31-12-2021mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☒Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission		Dy.No.25898 (R&I) dated 13-09-2022 Dy.No 29516 (R&I) dated 18-10-2022
	Details of fee submitted		**For transfer of registration:** PKR 30,000/-

		DS# 2458392360 deposited on 18-08-2022
	The proposed proprietary name / brand name	**Caflam 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sugar-coated tablet contains: Diclofenac Potassium 50mg
	Pharmaceutical form of applied drug	Reddish brown, round biconvex, sugar coated tablet.
	Pharmacotherapeutic Group of (API)	NSAIDs,Analgesic
	Reference to Finished product specifications	Manufacturers' Specifications (specs are same as previously notified vide No. F. 65-PRVC/202(PR-I) dated 16th August, 2021)
	Proposed Pack size	2 x 10's
	Proposed unit price	Already registered product
	The status in reference regulatory authorities	Voltaren Rapid 50mg Tablet, Novartis Pharmaceuticals Canada Inc., (Health Canada DIN 00881635)
	For generic drugs (me-too status)	Dyna-K 50mg Table, Akson Pharmaceuticals (Pvt) Ltd., Mirpur (Reg#023737)
	Name and address of API manufacturer.	Amoli Organics Private Limited Address: Plot No. 322/4, 40 Shed Area, G.I.D.C., Vapi , District-Valsad, State-Gujarat, INDIA
	1.5.11-Proposed Label	Same as already registered
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Diclofenac Potassium (DS) for its physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer Amoli organic is GMP certified and is responsible for all steps of manufacturing, packing and testing. Manufacturing process and process controls were briefly stated. Characterization elucidation studies was conducted using UV an NMR techniques. Degradation and process related impurities was listed and analyzed as per BP monograph and analysis of batch used in stability batches showed conformance defined specifications. DS manufacturers followed BP specification and accordingly analytical methods were verified. DS lot procured was analyzed by DP manufacturer. Working standards, container closure and stability studies summaries of 03 batches of Diclofenac Potassium were provided under Zone IV-b. Similarly, information summaries for drug product (caflam 50mg tab) related to its description, composition, choice of excipients, formulation

		development, manufacturing process, pharmaceutical equivalence and comparative dissolution profile against Caflam manufactured by GSK was provided. Justification for selection of manufacturing process and in-process controls, DP specification based on in-house / manufacturer's specification, excipients control as per pharmacopeia reference, analytical procedure and its validation, batch analysis, reference/working standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, synthesis process, manufacturer and manufacturing process, character elucidation using spectroscopy IR and NMR, physical form, polymorphism (no isomerism), structure elucidation using UV, FTIR, NMR, etc. Impurities based on BP, were analysed in 06 DS batches which remain in conformance to BP monograph. Inorganic impurities, residual solvents, genotoxic impurities were also studied. Based on a risk assessment study for arising nitrosamine impurities, firms deduced that there is no possibility for arising NMDA impurities in DS. DS specifications were based on the BP monograph. Analytical method and its verification were performed. DP manufacturer also performed analytical method verification of DS. Certificate of analysis of DS lot, batch analysis, reference standard and its CoA container closure system, specification and test methods for packing materials, and stability studies sheet were provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 36 months. DS was packed in a double HMHDPE bags in mini market pack and stored in well closed HDPE container. The DS remained stable and within specified limits as tested on defined intervals.
	Module-III Drug Product:	Firm has submitted data of drug product including its qualitative and quantitative composition, formulation development, manufacturing process development and in-process control, manufacturing process validation protocol and report, excipients testing methods based on pharmacopeia references with analysis reports, pharmaceutical equivalence and comparative dissolution profile, specifications and analytical procedures developed on the basis of in-house method and its validation studies, dissolution method validation, batch analysis,

<table>
<tr><td></td><td></td><td>justification of specifications, reference standard, container closure system and stability studies.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Caflam 50mg Tablet, manufactured by M/s GSK, which shows comparable results within specified limits.
The comparative dissolution profile was performed of the stability batch (BAC108) against the Caflam 50mg Tab (Batch XF5E) manufactured by GSK, Karachi. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 30 min, and at pH 7.5 for 90 minutes. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="4">i.</td><td rowspan="4">Acidic buffer (pH 1.2)</td><td>10 min</td><td>17.4 %</td><td>19.4 %</td></tr>
<tr><td>20 min</td><td>36.5 %</td><td>35.8 %</td></tr>
<tr><td>30 min</td><td>42.9 %</td><td>42.6 %</td></tr>
<tr><td colspan="3">f1 = 1.022
f2= 97.577</td></tr>
<tr><td rowspan="4">ii</td><td rowspan="4">Acetate buffer (pH 4.5)</td><td>10 min</td><td>53.3 %</td><td>52.9 %</td></tr>
<tr><td>20 min</td><td>59.3 %</td><td>60.3 %</td></tr>
<tr><td>30 min</td><td>66.5 %</td><td>67.3 %</td></tr>
<tr><td colspan="3">f1=0.776
f2=95.670</td></tr>
<tr><td rowspan="4">iii</td><td rowspan="4">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>43.9 %</td><td>43.7 %</td></tr>
<tr><td>20 min</td><td>94.1 %</td><td>93.9 %</td></tr>
<tr><td>30 min</td><td>102 %</td><td>101.9 %</td></tr>
<tr><td colspan="3">f1=0.776
f2=95.670</td></tr>
<tr><td rowspan="4">iv</td><td rowspan="4">Phosphate Buffer (pH 7.5)</td><td>70 min</td><td>83 %</td><td>83 %</td></tr>
<tr><td>80 min</td><td>97 %</td><td>97 %</td></tr>
<tr><td>90 min</td><td>99 %</td><td>99 %</td></tr>
<tr><td colspan="3">f1=0
f2=100</td></tr>
</table>
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed in-house manufacturer' specifications for which report of validation of analytical method for the drug product has been provided. Dissolution method validation studies were also provided.</td></tr>
</table>

STABILITY STUDY DATA

Manufacturer of API	Amoli Organics Private Limited Address: Plot No. 322/4, 40 Shed Area, G.I.D.C., Vapi , District-Valsad, State-Gujarat, INDIA
API Lot No.	DK/2107/0086B DK/2106/0059C
Description of Pack (Container closure system)	Alu-PVC blister packed along with patient information leaflet in a unit folding carton box, Pack Size : 20 tablets (2 x 10's).

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	BAC106	BAC107	BAC108
Batch Size	2,000,000 Tablets	2,000,000 Tablets	2,000,000 Tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	01-2022	01-2022	01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 20031925 issued by Food and Drug Control Administration, Gujrat State, India valid till 16/03/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API was purchased from Amoli Organics Pvt. Ltd. India, invoice dated 17-08-2021, cleared on 01-09-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

The drug substance for Caflam 50 mg Tablet is Diclofenac Potassium BP manufactured by Amoli Organics Pvt. Ltd. India.(GMP certified by Food and Drug Administration (Gujrat State) India). DS has no polymorphic form. The impurity profiling DS was carried as per BP monograph. Manufacturing and controls, comparability protocols, structural characterization, stability protocol and studies has been submitted. Specification is considered adequate with respect to BP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to provided specifications.

The drug product "Caflam" is sugar coated tablet of 50 mg of Diclofenac Potassium manufactured by Novartis Pharma Pakistan Ltd (Formerly Bayer Pakistan (Pvt.) Ltd. Karachi DML 000003 (Formulation). The method of manufacturing is granulation, compression and sugar coating with adequate in process controls. Submitted regulatory specifications are developed in–house which

were also previously notified by DRAP for GSK manufacturing site. Stability data shows no degradation product at specified time points.

M/s Novartis Pharma Pakistan Limited, (Formerly M/s Bayer Pakistan (Pvt.) Ltd.) is a GMP complaint unit as per certificate issued by DRAP, Karachi office based on the inspection conducted on 08-09-2021.

Caflam 50mg Tablets' pharmaceutical equivalence and comparative dissolution profile have been established against the existing registered product manufactured by M/s GSK, Karachi. The firm has submitted product leaflet which shows information related to clinical particulars and pharmacological properties of the Diclofenac potassium as stated for reference authority approved product based on the reliance principle. This product is mainly indicated for treatment of mild the short-term (up to one week) treatment of acute, mild to moderately severe pain.
The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.
The firm shall also ensure inclusion of warnings about the increase risk of serious cardiovascular adverse events with COX-2 inhibitors, and GI adverse events on the drug's label, in light with the reference product as approved by the Health Canada.

Proceedings of M-323:
The Board was informed that the applicant has also requested for conditional approval to produce few batches at existing manufacturing site (i.e., M/s GSK CHC, Jamshoro) due to following reason:

"Application for renewal of contract manufacturing permission of Caflam 50mg Tablet was considered by the Registration Board in its 321st meeting wherein approval was not granted for extension. However, the Board decided that the request of M/s. Novartis Pharma (Pakistan) Ltd., 15-West Wharf Dockyard Road, Karachi for registration of Caflam 50mg Tablets (021528) at their own facility shall be processed by the concerned registration section.

Please note that whenever there is such transfer from one site to another, production continues at the current site to avoid any shortages, however in this case GSK cannot manufacture further since approval letter is not issued for Caflam (i.e., Contract manufacturing permission expired in August 2022) and because of this Custom Authority is not releasing the API of this product since August 2022.

Therefore, even if the subject mentioned case is approved in 323rd meeting of Registration Board, it will take months to receive approval/ registration letter due to the regular process at DRAP. Additionally, once approval letter is received, it will take further few months to manufacture the product and supply in the market from new manufacturing site.

Furthermore, be informed that it has been over a month since production has stopped at GSK Jamshoro due to non-availability of API, this may create possible shortages in the market resulting in serious chaos among public."

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).

S. No.	Reg. No.	Product Name & Composition

1.	**021528**	**Caflam 50mg Tablets** **Each tablet contains: -** **Diclofenac Potassium……50mg** **(Manufacturer's Specification)**

ii. Approved registration of following product in the name of M/s Novartis Pharma Pakistan Limited, C-21, S.I.T.E Area, Karachi (DML#000003).

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

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name & Composition
1.	**Caflam 50mg Tablets** **Each sugar-coated tablet contains:** **Diclofenac Potassium……50mg**

iii. Approved "Manufacturer's Specifications" till the inclusion of more stringent specifications of the product in any official pharmacopeia of reference countries/ regulatory authorities as specified by the Registration Board in its 275th meeting.

Sr.#	Test Parameters	Manufacturer's Specification (Limits)
1.	**Identification of Diclofenac Potassium**	**By TLC: Corresponds to the reference** **By HPLC: Corresponds to the reference**
2.	**Identity of Potassium**	**Positive**
3.	**Identity of colorants** **Titanium** **Iron**	**Positive**
4.	**Dissolution of Diclofenac potassium after 90 minutes by UV (HCl buffer pH 1.2 & Phosphate buffer pH 7.5)**	***After 60 minutes:*** **Not more than 10% of the declared content.** ***After 90 minutes:*** **Not less than 75% (Q value) of the declared content, according to acceptance table of USP**
5.	**Uniformity of dosage units by Content Uniformity.**	**By HPLC & UV** **Meets the requirements of Ph.Eur., USP & JP**
6.	**Assay**	**By HPLC** **95.0 % - 105.0 % of the declared content**
7.	**Degradation products based on declared content of Diclofenac Potassium**	**By HPLC: Not more than 0.3%** **GP49002: Not more than 0.5%** **GP45828: Not more than 0.2%**

		GP49000: Not more than 0.2% **Other Individual Degradation products:** **Not more than 0.2%** **Total of other Degradation products:** **Not more than 0.3%**
8.	**Microbial enumeration tests (MET)** **1) Total aerobic microbial count (TAMC)** **2) Total yeasts & moulds count (TYMC)** **3) Specified micro-organism (E.coli)**	**1) Not more than 10^3 CFU/g** **2) Not more than 10^2 CFU/g** **3) Not detectable in 1 g**

iv. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.

Case No. 15. Request for Change in Registration Status of Products from M/s Novartis Pharma (Pakistan) Limited, Karachi to M/s AGP Limited B-23-C, S.I.T.E. Karachi (DML No. 000348)

M/s AGP Limited B-23-C, S.I.T.E. Karachi (DML No. 000348) has requested for change in registration status of following products from M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML # 000193) to their name. **The products were registered by way of contract manufacturing at M/s GSK Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro for period of 30months.**

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate M/s AGP Limited, B-23-C, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)
ii. Copy of DML of M/s AGP B-23-C, S.I.T.E. Karachi renewed w.e.f. 06-02-2020.
iii. Copy of approved sections by Central Licensing Board of M/s AGP Limited, B-23-C, S.I.T.E, Karachi confirming "Tablet (general)" section.
iv. NOC from M/s. Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi dated 23-06-2022.
v. Relevant undertakings & commitments.

I	**II**	**III**	**IV**
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Dy. No./ Fee/ Date Reg./Renewal status**
1.	018063	Nocid 20mg Tablets Each tablet contains: Famotidine……..20mg (USP Specification)	Dy.No.13364/R&I Dated 02-06-2022 Rs.30,000/- (DS#255926783613) Dated: 16-05-2022. DOR: 13-02-2020 Contract manufacturing permission valid upto 12-08-2022

2.	018064	Nocid 40mg Tablets Each tablet contains: Famotidine…….40mg (USP Specification)	Dy.No.13365/R&I Dated 02-06-2022 Rs.30,000/- (DS#47156551) Dated: 16-05-2022. DOR: 13-02-2020 Contract manufacturing permission valid upto 12-08-2022

The cases were referred to Pharmaceutical Evaluation Cell/ QMS for scrutinization/evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Evaluator: Mr. Abdul Mughees Mudassir (AD to CEO)

1.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Name, address of Manufacturing site.	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13365 dated 02/06/2022
	Details of fee submitted	PKR 30,000/-: dated 16/05/2022
	The proposed proprietary name / brand name	Nocid 20mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Famotidine……...20 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	H2-receptor antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	20’s
	Proposed unit price	As per DRAP approved price of Nocid 20mg Tablet
	The status in reference regulatory authorities	Famotidin-RatioPharm 20mg Tablet, RatioPharm
	For generic drugs (me-too status)	Acicon Tablet 20mg by M/s Barrett Hodgson Pakistan (Pvt.) Ltd., Reg. No. 024254
	GMP status of the Finished product manufacturer	GMP certificate granted on 17/06/2021

	Name and address of API manufacturer.	M/s Nakoda Chemicals Limited Address: Plot No. 64/A, Phase-I, IDA. Jeedimetla, Hyderabad – 500 055, Telangana, India. Phone: +91-40-23447755, 23447756, 23447757 Fax: +91-40-23447754
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Famotidine is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Accelerated: 40°C ± 2°C, 75%RH ± 5% Long-term: 30°C ± 2°C, 65%RH ± 5% Batches: FM 'P'/002/11 FM 'P'/003/11 FM 'P'/004/11
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Famotidin-RatioPharm 20mg Tablet by RatioPharm, Germany. CDP has been performed against the same brand that is Famotidin-RatioPharm 20mg Tablet by RatioPharm, Germany in pH 1.2, pH 4.5 & pH 6.8 released more than 85 % within 15minutes and comparative profile is similar.

	Analytical method validation/verification of product	Method verification studies have submitted.	
STABILITY STUDY DATA			
Manufacturer of API	M/s Nakoda Chemicals Limited Plot No. 64/A, Phase-I, IDA. Jeedimetla, Hyderabad – 500 055, Telangana, India.		
API Lot No.	FM-2106011U		
Description of Pack (Container closure system)	Alu/PVC blister of 2 x 10's tablets, packed in a secondary carton with a leaflet inside		
Stability Storage Condition	Accelerated stability study: 40°C ± 2°C / 75 ± 5% RH Long-term stability study: 30°C ± 2°C / 65 ± 5% RH		
Time Period	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Frequency	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Batch No.	21/054-STB/FAM-TAB/04	21/055-STB/FAM-TAB/05	21/056-STB/FAM-TAB/06
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	22-11-2021	22-11-2021	22-11-2021
No. of Batches	03		
Administrative Portion			
43.	Reference of previous approval of applications with stability study data of the firm (if any)		
44.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 65555/TS/2021 issued by DCA valid till 22/09//2024.	
45.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.2620/2021DRAP(K) dated 20/08/2021 is submitted for the permission to import femotidine for the purpose of trial, production, test and analysis is granted.	
46.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	

47.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
48.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		**Response of Firm**
Administrative Documents: • Valid NOC from Novartis for transfer of registration		The firm has submitted NOC from M/s. Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi dated 23-06-2022.
Technical Data: • The CDP submitted by the firm does not reflect percent coefficient of variation for Rt and Tt in all specified dissolution conditions. Firm was asked to provide the calculations to assess variability in results and overall determination of f1 and f2 values.		The firm has submitted RSD values (calculated for mean content dissolved at different time points) which are within acceptable range.
2.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Name, address of Manufacturing site.	M/s AGP Limited B-23-C, S.I.T.E., Karachi-75700, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13364 dated 02/06/2022
	Details of fee submitted	PKR 30,000/-: dated 16/05/2022
	The proposed proprietary name / brand name	Nocid 40mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Famotidine……...40 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	H2-receptor antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s
	Proposed unit price	As per DRAP approved price of Nocid 40mg Tablet

	The status in reference regulatory authorities	Famotidin-RatioPharm 40mg Tablet, RatioPharm.
	For generic drugs (me-too status)	Acicon Tablet 40mg by M/s Barrett Hodgson Pakistan (Pvt.) Ltd., Reg. No. 024253
	GMP status of the Finished product manufacturer	GMP certificate granted on 17/06/2021
	Name and address of API manufacturer.	M/s Nakoda Chemicals Limited Address: Plot No. 64/A, Phase-I, IDA. Jeedimetla, Hyderabad – 500 055, Telangana, India. Phone: +91-40-23447755, 23447756, 23447757 Fax: +91-40-23447754
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Famotidine is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Accelerated: 40°C ± 2°C, 75%RH ± 5% Long-term: 30°C ± 2°C, 65%RH ± 5% Batches: FM ‘P’/002/11 FM ‘P’/003/11 FM ‘P’/004/11
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product that is Famotidin-RatioPharm 40mg Tablet by RatioPharm, Germany

		CDP has been performed against the same brand that is Famotidin-RatioPharm 40mg Tablet by RatioPharm, Germany in pH 1.2, pH 4.5 & pH 6.8 released more than 85 % within 15minutes and comparative profile is similar. But percent co-efficient values have not been calculated.
	Analytical method validation/verification of product	Method verification studies have submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Nakoda Chemicals Limited Plot No. 64/A, Phase-I, IDA. Jeedimetla, Hyderabad – 500 055, Telangana, India.		
API Lot No.	FM-2106011U		
Description of Pack (Container closure system)	Alu/PVC blister of 1 x 10's tablets, packed in a secondary carton with a leaflet inside		
Stability Storage Condition	Accelerated stability study: 40°C ± 2°C / 75 ± 5% RH Long-term stability study: 30°C ± 2°C / 65 ± 5% RH		
Time Period	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Frequency	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Batch No.	21/051-STB/FAM-TAB/01	21/052-STB/FAM-TAB/02	21/053-STB/FAM-TAB/03
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	22-11-2021	22-11-2021	22-11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 65555/TS/2021 issued by DCA valid till 22/09//2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.2620/2021DRAP(K) dated 20/08/2021 is submitted for the permission to import femotidine for the purpose of trial, production, test and analysis is granted.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		**Response of Firm**
Administrative Documents: • Valid NOC from Novartis for transfer of registration		The firm has submitted NOC from M/s. Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi dated 23-06-2022.
Technical Data: • The CDP submitted by the firm does not reflect percent coefficient of variation for Rt and Tt in all specified dissolution conditions. Firm was asked to provide the calculations to assess variability in results and overall determination of f1 and f2 values.		The firm has submitted RSD values (calculated for mean content dissolved at different time points) which are within acceptable range.

Decision: Registration Board decided as under:

v. Cancelled registration of following products from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).

S. No.	Reg. No.	Product Name & Composition
3.	**018063**	**Nocid 20mg Tablets** **Each tablet contains:** **Famotidine……..20mg** **(USP Specification)**
4.	**018064**	**Nocid 40mg Tablets** **Each tablet contains:** **Famotidine…….40mg** **(USP Specification)**

vi. Approved registration of following products in the name of M/s AGP Limited B-23-C, S.I.T.E. Karachi (DML No. 000348).

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

d) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name & Composition
3.	**Nocid 20mg Tablets** **Each film coated tablet contains:** **Famotidine……..20mg** **(USP Specification)**
4.	**Nocid 40mg Tablets** **Each film coated tablet contains:** **Famotidine…….40mg** **(USP Specification)**

vii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.

Case No.16. Request for Change in Registration Status of Products from M/s Novartis Pharma (Pakistan) Limited, Karachi (contract manufactured by M/s GSK Consumer Healthcare Pakistan Ltd., Jamshoro) to M/s AGP Limited, B-23-C, S.I.T.E, Karachi

M/s. AGP Limited, B-23-C, S.I.T.E, Karachi has requested for change in registration of below mentioned products from M/s. Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No.000193)) to their name. **The products were registered by way of contract manufacturing at M/s GSK Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro for period of 30months.**

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting	
i.	Copy of registration letter and last renewal status.
ii.	Copy of DML of M/s AGP Limited, B-23-C, S.I.T.E, Karachi (Manufacturer) renewed w.e.f. 06-02-2020
iii.	Copy of approved sections by Central Licensing Board of M/s AGP Limited, B-23-C, S.I.T.E, Karachi confirming "Tablet (general)" section (Confirmed from letter dated 30-06-2020)
iv.	Copy of GMP inspection conducted on 06.07.2022, indicating "Good level" of compliance.
v.	NOC from Novartis Pharma (Pakistan) Limited, Karachi for transfer of products in the name of M/s AGP Limited, B-23-C, S.I.T.E dated 23-06-2022.
vi.	Relevant undertakings & commitments.

I	II	III	IV
S. No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Dy. No./ Fee/ Date Reg./Renewal status**
1.	007820	Clomfranil 10mg Tablets Each sugar coated tablet contains: Clomipramine Hydrochloride……..10mg (Manufacturer's Specification)	Dy.No.27317/R&I **27-09-2022** Rs.30,000/- (Invoice No. 820327578) DOR:22-01-2020

			Contract manufacturing permission valid upto 21-07-2022
2.	007821	Clomfranil 25mg Tablets Each sugar coated tablet contains: Clomipramine Hydrochloride……..25mg (Manufacturer's Specification)	Dy.No.27318/R&I **27-09-2022** Rs.30,000/- (Invoice No. 71554770820) DOR:22-01-2020 **Contract manufacturing permission valid upto 21-07-2022**

The cases were referred to Pharmaceutical Evaluation Cell/ QMS for scrutinization/evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Evaluator: Mst. Sana Kanwal (Evaluator-XX)

1.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
	Name, address of Manufacturing site.	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27317 dated 27/09/2022
	Details of fee submitted	PKR 30,000/- dated 13/09/2022
	The proposed proprietary name / brand name	Clomfranil 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Clomipramine Hydrochloride ….10mg
	Pharmaceutical form of applied drug	Light yellow colored triangular biconvex film coated tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Tricyclic Anti-depressant (Non-selective monoamine reuptake inhibitor)
	Reference to Finished product specifications	AGP Specifications
	Proposed Pack size	10×10's
	Proposed unit price	As per DRAP approved price of Clomfranil 10mg Tablet at the time of transfer of registration of product.
	The status in reference regulatory authorities	Anafranil 10mg tablet by M/s Apotex Inc, Approved by Health Canada

	For generic drugs (me-too status)	Anafril 10mg Tablet by M/s Glitz Pharma, Reg. No. 038578
	GMP status of the Finished product manufacturer	GMP inspection conducted on 06.07.2022 Tablet (General) section approved.
	Name and address of API manufacturer.	M/s. Sun Pharmaceutical Industries Ltd. Plot No. 24/2 & 25, Phase – IV, G.I.D.C. Industrial Zone, At & Post. Panoli – 394 116, Dist – Bharuch, Gujrat state, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Clomipramine HCl is present in EP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25°C ± 2°C / 60% ± 5% RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months (CLM/085, CLM/086, CLM/087)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Anafranil 10mg Tablet (Batch No 19L337) by Teofarma Turkey by performing quality tests (Identification, Assay, Disintegration time, Dissolution, Uniformity of dosage form).

		CDP has been performed against the same brand that is Anafranil 10mg Tablet by Teofarma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). on the basis of similarity factor (f2) result i.e NLT 50 of dissolution profile of both API in test product and reference product, both products are similar.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sun Pharmaceutical Industries Ltd. Plot No. 24/2 & 25, Phase – IV, G.I.D.C. Industrial Zone, At & Post. Panoli – 394 116, Dist – Bharuch, Gujrat state, India		
API Lot No.	PCCLMNF016		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (10×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months (continued till shelf life)		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21/039-STB/CLO-TAB/13	21/040-STB/CLO-TAB/14	21/041-STB/CLO-TAB/15
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	Oct-2021	Oct-2021	Oct-2021
Date of Initiation	15-10-2021	15-10-2021	15-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted previous reference of Azomax 500mg Tablet approved in Minutes of 316th meeting of Registration Board (15-18 March, 2022)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22073407 issued by Food and Drug Control Administration valid till 04/07/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.1252 dated 15-04-2021 is submitted wherein the permission to import API Clomipramine HCl (4kg) for the purpose of test/analysis and stability studies is granted. • Invoice no 7000061784 dated 31-3-2021

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

Remarks OF Evaluator[XX]:

Sr.#	Observation	Reply
1.	Stability data (real time) of Drug Substance has been submitted with 25°C ± 2°C / 65% ± 5% RH condition which is not as per WHO zone IV-A.	Firm has submitted Record of data logger for the storage conditions throughout the transportation. Real term stability studies data of the product for 12 months and forced degradation studies report (dated 02.05.2022) for the period of 6 months, has been submitted which was found satisfactory.

2.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
	Name, address of Manufacturing site.	M/s AGP Limited, B-23-C, S.I.T.E., Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 27318 dated 27/09/2022
	Details of fee submitted	PKR 30,000/-: dated 13/09/2022
	The proposed proprietary name / brand name	Clomfranil 25mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Clomipramine Hydrochloride….25mg

	Pharmaceutical form of applied drug	Light yellow colored round biconvex film coated tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Tricyclic Anti-depressant (Non-selective monoamine reuptake inhibitor)
	Reference to Finished product specifications	AGP Specifications
	Proposed Pack size	10×10's
	Proposed unit price	As per DRAP approved price of Clomfranil 25mg Tablet at the time of transfer of registration of product.
	The status in reference regulatory authorities	Anafranil 25mg tablet Health Canada
	For generic drugs (me-too status)	Depramine 25mg Tablet by M/s Hansel Pharmaceutical (Pvt) Ltd, Reg. No. 041350
	GMP status of the Finished product manufacturer	GMP inspection conducted on 06.07.2022 Tablet (General) section approved.
	Name and address of API manufacturer.	M/s. Sun Pharmaceutical Industries Ltd. Plot No. 24/2 & 25, Phase – IV, G.I.D.C. Industrial Zone, At & Post. Panoli – 394 116, Dist – Bharuch, Gujrat state, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Clomipramine HCl is present in BP/EP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25°C ± 2°C / 60% ± 5% RH for 72 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months (CLM/085, CLM/086, CLM/087)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Anafranil 25mg Tablet (Batch No 20F090) by Teofarma Turkey by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Anafranil 10mg Tablet by Teofarma in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). On the basis of similarity factor (f2) result i.e NLT 50 of dissolution profile of both API in test product and reference product, both products are similar.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s. Sun Pharmaceutical Industries Ltd. Plot No. 24/2 & 25, Phase – IV, G.I.D.C. Industrial Zone, At & Post. Panoli – 394 116, Dist – Bharuch, Gujrat state, India		
API Lot No.	PCCLMNF016		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (10×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	21/036-STB/CLO-TAB/10	21/037-STB/CLO-TAB/11	21/038-STB/CLO-TAB/12
Batch Size	8000 Tablets	8000 Tablets	8000 Tablets
Manufacturing Date	October -2021	October -2021	October -2021
Date of Initiation	12-10-2021	12-10-2021	12-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted previous reference of Azomax 500mg Tablet approved in Minutes of 316th meeting of Registration Board (15-18 March, 2022)
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22073407 issued by Food and Drug Control Administration valid till 04/07/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.1252 dated 15-04-2021 is submitted wherein the permission to import API Clomipramine HCl (4kg) for the purpose of test/analysis and stability studies is granted. • Invoice no 7000061784 dated 31-3-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliant
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator[XX]:

Sr.#	Observation	Reply
1.	Stability data (real time) of Drug Substance has been submitted with 25°C ± 2°C / 65% ± 5% RH condition which is not as per WHO zone IV-A.	Firm has submitted Record of data logger for the storage conditions throughout the transportation. Real term stability studies data of the product for 12 months and forced degradation studies report (dated 02.05.2022) for the period of 6 months, has been submitted which was found satisfactory.

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).

S. No.	Reg. No.	Product Name & Composition
1.	**007820**	**Clomfranil 10mg Tablets** **Each sugar coated tablet contains:** **Clomipramine Hydrochloride……..10mg**

		(Manufacturer's Specification)
2.	**007821**	**Clomfranil 25mg Tablets** **Each sugar coated tablet contains:** **Clomipramine Hydrochloride……..25mg** **(Manufacturer's Specification)**

ii. Approved registration of following products in the name of M/s AGP Limited B-23-C, S.I.T.E. Karachi (DML No. 000348).

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

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name & Composition
1.	**Clomfranil 10mg Tablets** **Each film coated tablet contains:** **Clomipramine Hydrochloride……..10mg**
2.	**Clomfranil 25mg Tablets** **Each film coated tablet contains:** **Clomipramine Hydrochloride……..25mg**

iii. The applicant shall submit fee of Rs. 7500/-each (in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021) for pre-registration variation/ change in finished product specifications from "AGP Specifications" to "As per Innovator's Specifications".

iv. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.

v. The Board further decided that registration letter shall be issued after regularization of registrations of above-mentioned products under SRO 1005(I)/2017.

Case No.17. Request for Change in Registration Status of Products from M/s Novartis Pharma (Pakistan) Limited, Karachi (contract manufactured by M/s Global Pharmaceuticals (Pvt.) Ltd., Islamabad) to M/s AGP Limited, B-23-C, S.I.T.E, Karachi

M/s. AGP Limited, B-23-C, S.I.T.E, Karachi (DML No.000348) has requested for change in registration status of below mentioned products from M/s. Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No.000193) to their name. **The products are currently registered by way of contract manufacturing at M/s Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad (DML No. 000417) and permission is valid till 30-06-2025.**

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting

i. Copy of registration letter and last renewal status.
ii. Copy of DML of M/s AGP Limited, B-23-C, S.I.T.E, Karachi (Manufacturer) renewed w.e.f. 06-02-2020
iii. Copy of approved sections by Central Licensing Board of M/s AGP Limited, B-23-C, S.I.T.E, Karachi confirming "Tablet (general)" section (Confirmed from letter dated 30-06-2020)
iv. Copy of GMP certificate M/s AGP Limited, B-23-C, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)
v. NOC from Novartis Pharma (Pakistan) Limited, Karachi dated 23-06-2022
vi. Application with Form-5F and required fee as per relevant SRO.
vii. Relevant undertakings & commitments.

The cases were referred to QMS for scrutinization/evaluation. Detail of submitted documents remarks of evaluators have been mentioned as under:

Evaluator: Mst. Urooj Fatima (AD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	030510	Levofin 250mg Tablets Each film coated tablet contains: Levofloxacin……250mg	Initial Reg. Date in name of M/s Global Pharma: **19-05-2003** Grant of registration in name of M/s Novartis Pharma (Pakistan) Limited, Karachi on contract manufacturing basis from M/s Global Pharma, Islamabad: **24-07-2009 (Valid till 30-06-2010)** Extension in contract mfg. permission granted on **18-06-2015 (Valid till 30-06-2015)** Renewal applied: **10-07-2019** Last Extension in contract mfg. permission granted **on 15-09-2020 (Valid till 30-06-2025)**
	Name, address of Applicant / Marketing Authorization Holder		M/s. AGP Limited, B-23-C, S.I.T.E, Karachi **DML # 000348**
	Name, address of Manufacturing site.		M/s AGP Limited, B-23-C, S.I.T.E, Karachi **(DML# 000348)**
	Status of the applicant		☒**Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		Copy of GMP certificate M/s AGP Limited, B-23-C, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)
	Evidence of approval of manufacturing facility		Applicant has provided copy of GMP certificate mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale

		☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No.19179 (R&I) dated 30-06-2022
	Details of fee submitted	**For transfer of registration:** PKR. 30,000/- DS# 3825887847 dated 14-06-2022
	The proposed proprietary name / brand name	**Levofin 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin (as hemihydrate)……250mg
	Pharmaceutical form of applied drug	Orange coloured oblong biconvex film coated scored tablet plain on other side.
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Levofloxacin 250mg Tablet, Teva Pharma (USFDA)
	For generic drugs (me-too status)	Effiflox 250mg Tablet, Sami Pharmaceuticals (Pvt) Ltd. (Reg#037709)
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co. Ltd, No. 31 Weisan Road, Hangzhou Bay, Shangyu Economic and Technological Development Area, Zhejiang, China.
	1.5.11-Proposed Label	**Not Submitted**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Levofloxacin hemihydrate, related structure, solubilities, and other general properties, manufacturing site, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, refence standard, container closure and stability studies summaries of Levofloxacin hemihydrate. Similarly, information summaries for drug product (Levofin) including its description, composition, pharmaceutical development, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has

<table>
<tr><td></td><td></td><td>been provided.</td></tr>
<tr><td></td><td>Module-III Drug Substance:</td><td>Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis, impurity profiling of all pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin), specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and stability studies with study protocol.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 60 months. DS was packed in a double layered LDPE bag and packaged again in cardboard drums. The DS remained within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Leflox 250mg Tablet of M/s Getz Pharma, Pakistan which shows comparable results within specified limits.
The comparative dissolution profile was performed for Levofin 250mg Tablet against the Leflox 250mg Tablet of M/s Getz Pharma, Pakistan. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 45mins. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Leflox Tab</th><th>Levofin Tab</th></tr>
<tr><td>i.</td><td></td><td>10 min</td><td>89.8%</td><td>100.2%</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td></td><td>Acidic buffer (pH 1.2)</td><td>15 min</td><td>100.6%</td><td>100.3%</td></tr>
<tr><td></td><td></td><td>30 min</td><td>100.6%</td><td>100.1%</td></tr>
<tr><td></td><td></td><td>45 min</td><td>99.7%</td><td>100.4%</td></tr>
<tr><td></td><td></td><td colspan="3"></td></tr>
<tr><td>ii</td><td>Acetate buffer (pH 4.5)</td><td>10 min</td><td>96.3%</td><td>100.2%</td></tr>
<tr><td></td><td></td><td>15 min</td><td>97.5%</td><td>100.6%</td></tr>
<tr><td></td><td></td><td>30 min</td><td>97.9%</td><td>100.9%</td></tr>
<tr><td></td><td></td><td>45 min</td><td>98.9%</td><td>101.3%</td></tr>
<tr><td></td><td></td><td colspan="3"></td></tr>
<tr><td>iii.</td><td>Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>85.6%</td><td>96.8%</td></tr>
<tr><td></td><td></td><td>15 min</td><td>96.1%</td><td>99.3%</td></tr>
<tr><td></td><td></td><td>30 min</td><td>98.6%</td><td>99.8%</td></tr>
<tr><td></td><td></td><td>45 min</td><td>98.2%</td><td>99.5%</td></tr>
<tr><td></td><td></td><td colspan="3"></td></tr>
</table>
f1 and f2 value has not been calculated because both reference and test sample achieved 85% dissolution within 15 minutes, hence, comparative profile is considered similar.
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided. Analytical methods verification was performed in January, 2022. Dissolution method verification protocol and study report were also provided.</td></tr>
</table>

<table>
<tr><td colspan="4">STABILITY STUDY DATA</td></tr>
<tr><td>Manufacturer of API</td><td colspan="3">Shangyu Jingxin Pharmaceutical Co. Ltd, No. 31 Weisan Road, Hangzhou Bay, Shangyu Economic and Technological Development Area, Zhejiang, China.</td></tr>
<tr><td>API Lot No.</td><td colspan="3">DK21-2106161</td></tr>
<tr><td>Description of Pack (Container closure system)</td><td colspan="3">Alu/Alu blister of 1x10’s in secondary carton</td></tr>
<tr><td>Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 65% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td>Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td>Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, (Months) (Continued for 24 months)</td></tr>
<tr><td>Batch No.</td><td>21/042-STB/LEV-TAB/01</td><td>21/043-STB/LEV-TAB/02</td><td>21/044-STB/LEV-TAB/03</td></tr>
<tr><td>Batch Size</td><td>3500 Tablets</td><td>3500 Tablets</td><td>3500 Tablets</td></tr>
<tr><td>Manufacturing Date</td><td>10-2021</td><td>11-2021</td><td>11-2021</td></tr>
<tr><td>Date of Initiation</td><td>09-11-2021</td><td>09-11-2021</td><td>09-11-2021</td></tr>
<tr><td>No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="4">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
</table>

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted: Copy of GMP certificate (Certificate No. ZJ20190157) issued by National Medical Products Administration China, dated 30-11-2019. (Valid up to 29-11-2024). Copy of DML (No. Zhe 20050427) issued by Zhejiang Medical Products Administration issued on 22-03-2020 (Valid until; 21-02-2025)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from M/s Sunmore Healthcare Co. Ltd, Hunan, China (manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China verified through COA and GMP certificate of manufacturer). invoice dated 02-08-2021, cleared 16-08-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

The drug substance for Levofin 250mg Tablet (Levofloxacin hemihydrate) is manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China. (GMP certified by National Medical Products Administration China) on USP specifications. The impurity profiling of DS is also carried out for pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin). Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to USP specifications.

The drug product is film coated tablet of 250mg manufactured by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) (Formulation) (orange coloured oblong biconvex film coated scored tablet plain on other side). The method of manufacturing is wet granulation and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

Analytical methods verification was performed in January, 2022, whereas product is manufactured and tested in October / November, 2021. However, testing was performed as per USP specifications.

M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) is a GMP complaint unit as per certificate issued by DRAP, Karachi office based on inspection conducted on 03-06-2021. (Validity 02 years).

Levofin 250mg Tablets' pharmaceutical equivalence has been established against the Leflox 250mg Tablet of M/s Getz Pharma, which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Leflox 250mg Tablet of M/s Getz. The clinical particulars and pharmacological properties of the Levofloxacin, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for acute bacterial sinusitis, uncomplicated cystitis, acute exacerbation of COPD including bronchitis, complicated skin and soft tissue infections / complicated skin and skin structure infections.

Conclusion:

The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.

The firm shall also ensure black boxed information on "Serious Adverse Reactions Including Tendinitis, Tendon Rupture, Peripheral Neuropathy, Central Nervous System Effects and Exacerbation of Myasthenia Gravis" in the beginning of the leaflet.

S.No.	Reg. No.	Registered Brand Name & Composition of Product	Registration Trail
2.	030511	Levofin 500mg Tablets Each film coated tablet contains: Levofloxacin……500mg	Initial Reg. Date in name of M/s Global Pharma: **19-05-2003** Grant of registration in name of M/s Novartis Pharma (Pakistan) Limited, Karachi on contract manufacturing basis from M/s Global Pharma, Islamabad: **24-07-2009 (Valid till 30-06-2010)** Extension in contract mfg. permission granted on **18-06-2015 (Valid till 30-06-2015)** Renewal applied: **10-07-2019** Last Extension in contract mfg. permission granted **on 15-09-2020 (Valid till 30-06-2025)**
	Name, address of Applicant / Marketing Authorization Holder		M/s. AGP Limited, B-23-C, S.I.T.E, Karachi **DML # 000348**
	Name, address of Manufacturing site.		M/s AGP Limited, B-23-C, S.I.T.E, Karachi **(DML# 000348)**
	Status of the applicant		☒**Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		Copy of GMP certificate M/s AGP Limited, B-23-C, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)
	Evidence of approval of manufacturing facility		Applicant has provided copy of GMP certificate mentioning Tablet (General) section among Formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No.19180 (R&I) dated 30-06-2022
	Details of fee submitted	**For transfer of registration:** PKR. 30,000/- DS# 911353169 dated 14-06-2022
	The proposed proprietary name / brand name	**Levofin 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin (as hemihydrate)……500mg
	Pharmaceutical form of applied drug	White to off white coloured oblong biconvex film coated scored tablet plain on other side.
	Pharmacotherapeutic Group of (API)	Fluoroquinolone antibiotics
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Levofloxacin 500mg Tablet, Teva Pharma (USFDA)
	For generic drugs (me-too status)	Tavanic 500mg Tablet, Sanofi Aventis. (Reg#022242)
	Name and address of API manufacturer.	Shangyu Jingxin Pharmaceutical Co. Ltd, No. 31 Weisan Road, Hangzhou Bay, Shangyu Economic and Technological Development Area, Zhejiang, China.
	1.5.11-Proposed Label	**Not Submitted**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Levofloxacin hemihydrate, related structure, solubilities, and other general properties, manufacturing site, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, refence standard, container closure and stability studies summaries of Levofloxacin hemihydrate. Similarly, information summaries for drug product (Levofin) including its description, composition, pharmaceutical development, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard,

<table>
<tr><td></td><td></td><td>container closure system and stability studies has been provided.</td></tr>
<tr><td></td><td>Module-III Drug Substance:</td><td>Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis, impurity profiling of all pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin), specifications based on USP, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and stability studies with study protocol.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months. DS was packed in a double layered LDPE bag and packaged again in cardboard drums. The DS remained within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its verification, dissolution method verification, batch analysis, justification of specifications, USP procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to USP.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Tavanic 500mg Tablet of M/s Sanofi Aventis, Germany which shows comparable results within specified limits.
The comparative dissolution profile was performed for Levofin 500mg Tablet against the Tavanic 500mg Tablet of M/s Sanofi Aventis, Germany. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 45mins. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Media</th><th>Time interval</th><th>Tavanic Tab</th><th>Levofin Tab</th></tr>
<tr><td>i.</td><td></td><td>10 min</td><td>77.8%</td><td>85.7%</td></tr>
</table>
</td></tr>
</table>

			Acidic buffer (pH 1.2)	15 min	98.9%	97.3%
				30 min	99.4%	97.1%
				45 min	99.1%	96.7%
		ii	Acetate buffer (pH 4.5)	10 min	74.3%	90%
				15 min	96.5%	94%
				30 min	97.7%	95.6%
				45 min	98.1%	95.9%
		iii.	Phosphate Buffer (pH 6.8)	10 min	78.3%	85.4%
				15 min	98.4%	96.1%
				30 min	99.4%	98%
				45 min	99.3%	97.9%
		f1 and f2 value has not been calculated because both reference and test sample achieved 85% dissolution within 15 minutes, hence, comparative profile is considered similar.				
	Analytical method validation/verification of product	Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided**. Analytical methods verification was performed in January, 2022.** Dissolution method verification protocol and study report were also provided.				

STABILITY STUDY DATA			
Manufacturer of API	Shangyu Jingxin Pharmaceutical Co. Ltd, No. 31 Weisan Road, Hangzhou Bay, Shangyu Economic and Technological Development Area, Zhejiang, China.		
API Lot No.	DK21-2106161		
Description of Pack (Container closure system)	Alu/Alu blister of 1x10's in secondary carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months) (Continued for 24 months)		
Batch No.	21/067-STB/LEV-TAB/01	21/068-STB/LEV-TAB/02	21/069-STB/LEV-TAB/03
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	18-12-2021	18-12-2021	18-12-2021
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted: Copy of GMP certificate (Certificate No. ZJ20190157) issued by National Medical Products Administration China, dated 30-11-2019. (Valid up to 29-11-2024). Copy of DML (No. Zhe 20050427) issued by Zhejiang Medical Products Administration issued on 22-03-2020 (Valid until; 21-02-2025)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from M/s Sunmore Healthcare Co. Ltd, Hunan, China (manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China verified through COA and GMP certificate of manufacturer). Invoice dated 02-08-2021, cleared 16-08-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator:

The drug substance for Levofin 500mg Tablet (Levofloxacin hemihydrate) is manufactured by Shangyu Jingxin Pharmaceutical Co. Ltd, Zhejiang, China. (GMP certified by National Medical Products Administration China) on USP specifications. The impurity profiling of DS is also carried out for pharmacopeial listed impurities (Levofloxacin related compound A, Diamine derivative, Levofloxacin-N-oxide, Decarboxy Levofloxacin). Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per USP monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to USP specifications.

The drug product is film coated tablet of 500mg manufactured by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) (Formulation) (white to off-white coloured oblong biconvex film coated scored tablet plain on other side). The method of manufacturing is wet granulation and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per USP monograph and submitted stability data shows no degradation product at specified time points.

Analytical methods verification was performed in January, 2022, whereas product is manufactured and tested in October / November, 2021. However, testing was performed as per USP specifications.

M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) is a GMP complaint unit as per certificate issued by DRAP, Karachi office based on inspection conducted on 03-06-2021. (Validity 02 years).

Levofin 500mg Tablets' pharmaceutical equivalence has been established against the Tavanic 500mg Tablet of M/s Sanofi Aventis, Germany, which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Tavanic 500mg Tablet of M/s Sanofi Aventis, Germany. The clinical particulars and pharmacological properties of the Levofloxacin, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for acute bacterial sinusitis, uncomplicated cystitis, acute exacerbation of COPD including bronchitis, complicated skin and soft tissue infections / complicated skin and skin structure infections.

Conclusion:

The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.

The firm shall also ensure black boxed information on "Serious Adverse Reactions Including Tendinitis, Tendon Rupture, Peripheral Neuropathy, Central Nervous System Effects and Exacerbation of Myasthenia Gravis" in the beginning of the leaflet.

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
3.	054727	Acemed 100mg Tablets Each film coated tablet contains: - Aceclofenac……100mg	Initial Reg. Date in name of M/s Global Pharma: **01-01-2009** Grant of registration in name of M/s Novartis Pharma (Pakistan) Limited, Karachi on contract manufacturing basis from M/s Global Pharma, Islamabad: **24-07-2009 (Valid till 30-06-2010)** Extension in contract mfg. permission granted on **18-06-2015 (Valid till 30-06-2015)** Renewal applied: **10-07-2019** Last Extension in contract mfg. permission granted **on 15-09-2020 (Valid till 30-06-2025)**
	Name, address of Applicant / Marketing Authorization Holder		M/s AGP Limited, B-23-C, S.I.T.E, Karachi **(DML# 000348)**
	Name, address of Manufacturing site.		M/s AGP Limited, B-23-C, S.I.T.E, Karachi **(DML# 000348)**
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		Copy of last inspection report conducted on 06-07-2022 provided wherein it was concluded that firm was observed to be maintained at good level of GMP compliance. GMP certificate M/s AGP Limited, B-23-C, S.I.T.E, Karachi on the basis of inspection conducted on 03-06-2021. (Validity 02 years)

	Evidence of approval of manufacturing facility	Applicant has provided copy of GMP certificate mentioning Tablet (General) section among Formulation sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No.27810 (R&I) dated 30-09-2022
	Details of fee submitted	**For transfer of registration:** PKR. 30,000/- DS# 830091530 dated 16-09-2022
	The proposed proprietary name / brand name	**Acemed 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Aceclofenac……100mg
	Pharmaceutical form of applied drug	Reddish brown coloured, round biconvex film coated plain on both sides.
	Pharmacotherapeutic Group of (API)	Non-Steroidal Anti-Inflammatory Drug (NSAID)
	Reference to Finished product specifications	In-house Specifications
	Proposed Pack size	1 x 10's
	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Aceclofenac 100mg film coated Tablet, Accord Healthcare (EMA)
	For generic drugs (me-too status)	Alkeris 100mg Tablet, Sami Pharmaceuticals (Pvt) Ltd. (Reg#047344)
	Name and address of API manufacturer.	Jingxi Synergy Pharmaceutical, Co., Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, China
	1.5.11-Proposed Label	**Not Submitted**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Aceclofenac, related structure, solubilities, and other general properties, manufacturing site, character elucidation, impurities characterizations, specifications based on Eur. Ph, analytical procedures and its validation, batch analysis, reference standard, container closure and stability studies summaries of Aceclofenac. Similarly, information summaries for drug product (Acemed) including its description, composition,

		pharmaceutical development, pharmaceutical equivalence against Beofenac 100mg Tablet of M/s Almirall S.A, comparative dissolution profile, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DS and DP manufacturer, certificate of analysis, impurities, specifications based on Eur. Ph, analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and test methods for packing materials, and stability studies with study protocol.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 25ºC ± 2ºC / 60% ± 5% RH for 72 months.** DS was packed in a double layered LDPE bag and packaged again in fiber drums. The DS remained within specified limits as tested on defined intervals. DS manufacturer also conducted forced degradation studies under stress conditions including acidic, basic, oxidative, thermal and photolytic degradation, which resolve the stability of API. Temperature data log for transportation of API were also provided.
	Module-III Drug Product:	Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its validation, dissolution method validation, batch analysis, characterization of impurities, forced degradation studies, justification of specifications, reference standard or materials, container closure system and stability. The Specifications and control tests comply to in house specifications.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Beofenac 100mg Tablet of M/s Almirall S.A.

(Spain) which shows comparable results within specified limits.
The comparative dissolution profile was performed for Acemed 100mg Tablet against the Beofenac 100mg Tablet of M/s Almirall S.A. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 45mins. Calculation of value is as under:

Sr	Mediums	Time interval	Beofenac Tab	Acemed Tab
i.	Acidic buffer (pH 1.2)	10 min	1%	1.2%
		15 min	1.8%	1.7%
		30 min	2.5%	2.1%
		45 min	2.4%	2.1%
ii	Acetate buffer (pH 4.5)	10 min	24%	34.8%
		15 min	37.4%	43.4%
		30 min	52.1%	55.8%
		45 min	60.1%	62.5%
iii.	Phosphate Buffer (pH 6.8)	10 min	68.2%	97.1%
		15 min	91.3%	99.1%
		30 min	97.5%	98.3%
		45 min	97.4%	95.6%

f1 and f2 value has not been calculated for pH 6.8 because both reference and test sample achieved 85% dissolution within 15 minutes. For pH 1.2 and 4.5, F2 has been calculated which is 99.2 and 58.9, respectively. On the basis of similarity factor results (not less than 50) both reference and test products are found similar.

Analytical method validation/verification of product	Firm has claimed In-house specifications for which report of validation of analytical method for the drug product has been provided**.** Dissolution method verification protocol and study report were also provided.

STABILITY STUDY DATA

Manufacturer of API	Jingxi Synergy Pharmaceutical, Co., Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, China
API Lot No.	20200801B
Description of Pack (Container closure system)	Alu/Alu blister of 1x10's in secondary carton
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) (Continued for 24 months) Real Time: 0, 3, 6, (Months)		
Batch No.	22/021-STB/ACE-TAB/01	22/022-STB/ACE-TAB/02	22/023-STB/ACE-TAB/03
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (Certificate No. 2022001) issued by Jiangxi API Engineering Technology Research Centre, China, dated 20-01-2022. (Valid up to 19-01-2027).
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API purchased from Jingxi Synergy Pharmaceutical, Co., Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, China. Invoice dated 10-09-2021, cleared 16-09-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

The drug substance for Acemed 100mg Tablet (Aceclofenac) is manufactured by Jingxi Synergy Pharmaceutical, Co., Ltd. Jiangxi Fengxin Industrial Park, Fengxin, Jiangxi Province, China (GMP certified by Jiangxi API Engineering Technology Research Centre, China) on Eur. Ph. specifications. The impurity profiling of DS is also carried out. Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification is as per Eur. Ph. monograph. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to Eur.Ph / BP specifications.

The drug product is film coated tablet of 100mg manufactured by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) (Formulation) (Reddish brown coloured, round biconvex film coated plain on both sides). The method of manufacturing is granulation, direct compression and film coating with adequate process controls at critical points. Submitted regulatory specifications are In-house and submitted stability data shows no degradation product at specified time points.

M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML# 000348) is a GMP complaint unit as per certificate issued by DRAP, Karachi office based on inspection conducted on 03-06-2021. (Validity 02 years).

Acemed 100mg Tablets' pharmaceutical equivalence has been established against the Beofenac 100mg Tablet of M/s Almirall S.A which shows comparable results within specified limits. Comparative dissolution profile was conducted against the Beofenac 100mg Tablet of M/s Almirall S.A. The clinical particulars and pharmacological properties of the Aceclofenac, based on the reliance principle, are as per the reference regulatory authority's product. This product is mainly indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

Conclusion:
The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).

S. No.	Reg. No.	Product Name & Composition
1.	030510	Levofin 250mg Tablets Each film coated tablet contains: Levofloxacin……..250mg
2.	030511	Levofin 500mg Tablets Each film coated tablet contains: Levofloxacin……..500mg
3.	054727	Acemed 100mg Tablets Each film coated tablet contains: - Aceclofenac……100mg

ii. Approved registration of following products in the name of M/s AGP Limited B-23-C, S.I.T.E. Karachi (DML No. 000348).

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

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

c) For product at S. No. 3 of below table, the applicant shall submit fee of Rs. 7500/- (in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021) for pre-registration variation/ change in finished product specifications from "In house Specifications" to "As per Innovator's Specifications".

S. No.	Product Name & Composition
1.	Levofin 250mg Tablets Each film coated tablet contains:

	Levofloxacin (as Hemihydrate)……250mg **(USP Specifications)**
2.	**Levofin 500mg Tablets** **Each film coated tablet contains:** **Levofloxacin (as Hemihydrate)…….…500mg** **(USP Specifications)**
3.	**Acemed 100mg Tablets** **Each film coated tablet contains: -** **Aceclofenac……..……100mg** **(As per Innovator's Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.

Case No.18: Approved Product of M/s Mediate Pharmaceutical (Pvt) Ltd. Karachi

Registration Board in its 237th meeting (held on 26-02-2013) approved the following products of M/s Mediate Pharmaceutical (Pvt) Ltd. Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi as per details mentioned vide column II & III of below table. The firm has now requested for issuance of registration & submitted requisite fee along-with required documents/ information as per detail recorded vide Column IV of below table:

S/ N	Product Name & Composition	Decision of RB-237	Current Status/ Documents Submitted by the Firm	RRA & Generic Status/ Remarks
I	**II**	**III**	**IV**	**V**
1.	M-Plate Plus Tablets Each tablet contains:- Clopidogrel ……..75mg Aspirin ……75mg (Anticoagulants/platelet aggregation) <u>Demanded MRP/Pack:</u> Rs.200/10's	Approved subject to confirmation of manufacturing facility for bi layered tablet and payment of differential fee	• Dy.No.11518/R&I dated 12-05-2022 & 34540/ R&I dated 29-11-2022 • Differential registration fee of Rs.22000/-(DS#498618250 dated 09-05-2022) • Pre-registration variation fee of Rs.2x30000/- (DS#47326650474 & 6558788186 dated 25-11-2022) for correction in composition as per RRA. Correct composition is: *Each film coated bi-layered tablet contains:-* *Clopidogrel (as hydrogen sulphate)……..75mg* *Aspirin ……75mg* • Correct form-5, Master formulation & manufacturing method. • FPP Specifications; As per Innovator's.	• EMA Approved • Clobis Plus Tablet by M/s Genome.

			• IQ, OQ & PQ report along-with invoice of ZP-420-28D Double Rotary Compression Machine. • Last Inspection Report 17-12-2021.(Acceptable Level of Compliance) • Renewal of DML issued vide Licensing Division's letter dated 15-09-2021 stating approval of "Tablet (General) Section"	

Decision: Registration Board approved registration of above-mentioned product in the name of M/s Mediate Pharmaceutical (Pvt) Ltd. Plot No. 150-151 Sector 24 Korangi Industrial Area Karachi.

Case No.19. Request for Change in Registration Status of Products from M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) to M/s Sami Pharmaceuticals Pvt Ltd., Plot No. F-140/A, off Hub, River Road, S.I.T.E, Karachi (DML#000938).

M/s Sami Pharmaceuticals Pvt Ltd., Plot No. F-140/A, S.I.T.E, Karachi (DML No.000938) has requested for change in registration status of below mentioned products from M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) to their name.

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of registration letters and last renewal status.
ii. Copy of DML of M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, S.I.T.E, Karachi (DML#000938) issued on 13-09-2021.
iii. Copy of approval letter (dated 13-09-2021) for issuance of DML (No.000938; by way of formulation) confirming "Spansules (General)".
iv. NOC from M/s. Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072) to transfer TEpH (40mg and 20mg) Capsule to the M/s Sami Pharmaceuticals Pvt Ltd., Plot No. F -140/A, off Hub, River Road S.I.T.E, Karachi (DML#000938) issued on 23-08-2022
v. Relevant undertakings & commitments.

The cases were referred to QMS for evaluation. Detail of submitted documents and remarks of evaluator have been mentioned as under:

Evaluator: Mr. Asadullah (AD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	025595	TEpH 40mg Capsules	Initial Reg. Date: **30-03-2000** Renewal of Registration **07-04-2010**

		Each capsules contains: - Omeprazole enteric coated pellets equivalent to Omeprazole 40mg (USP Specifications)	Last Renewal Submitted on: **21-01-2020** (Change of FPP Specification were also granted on 17-03-2022 from Manufacturers' specification to USP Specification) Remarks of RRR Section: Renewal application was received on 21-01-2020 i.e., within time w.r.t. date of registration.
	Name, address of Applicant / Marketing Authorization Holder		M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, Off Hub, River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.		**M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, Off Hub, River Road, S.I.T.E, Karachi (DML#000938)**
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		New License
	Evidence of approval of manufacturing facility		DML issuance covering letter dated 13-09-2021 confirming Spansules (General) as formulation section
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☒Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission		Dy.No.26508 (R&I) dated 19-09-2022
	Details of fee submitted		**For transfer of registration:** PKR 150,000/- DS# 33324885 deposited on 17-08-2022
	The proposed proprietary name / brand name		**TEpH 40mg Capsules (Reg. No. 025595)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each capsule contains: Enteric coated pellets of Omeprazole equivalent to omeprazole USP …..40mg
	Pharmaceutical form of applied drug		Hard Gelatin capsule Size No. 1 having ivory opaque cap and chocolate brown opaque body containing white to off white enteric coated pellets.
	Pharmacotherapeutic Group of (API)		Proton Pump Inhibitor
	Reference to Finished product specifications		USP Specifications
	Proposed Pack size		14's
	Proposed unit price		Already registered product
	The status in reference regulatory authorities		Losec 40mg Capsule, (EMA approved)
	For generic drugs (me-too status)		Risek 40mg Capsules, manufactured by Getz Pharma, Karachi (Reg# 022109)

	Name and address of API manufacturer.	Murli Krishna Pharma Private Limited Address: D-98, Ranjangaon MDIC, Ranjangoan, Taluka – Shirur – Pune, Maharashtra, INDIA
	1.5.11-Proposed Label	Same as already registered
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Monograph of omeprazole for DS and FPP are available in USP. Firm has summarized information of omeprazole (DS) for its nomenclature, physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer Murli Krishna is GMP certified and is responsible for all steps of manufacturing, packing and quality testing. Characterization elucidation studies was conducted using IR, NMR mass spectrum and UV absorption techniques. Potential organic impurities related to API was listed with their structure and acceptance criteria. However, during batch analysis, impurities were analyzed as per USP monograph and analysis of batch used in stability batches showed conformance to defined specifications. DS manufacturers followed in-house specification and accordingly analytical methods were developed and validated. DS lot procured was analyzed by DP manufacturer. Working standards, container closure and stability studies summaries of 03 batches were provided under Zone IV-b. Similarly, information summaries for drug product related to its description, composition, formulation development, manufacturing process, pharmaceutical equivalence and comparative dissolution profile against Losec capsules manufactured by AstraZeneca UK were provided. Development of manufacturing process and in-process controls, batch formula, DP specification based on USP specification, excipients control as per pharmacopeia reference, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided. BMR of three stability batches were also provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, Character elucidation using spectroscopy IR and NMR, physical form, polymorphism (no isomerism), structure elucidation using UV, NMR, etc. were provided. Manufacturing process development, critical process steps and intermediate were identified. DS specifications were based on the inhouse method and accordingly analytical method were developed and its validating studies were performed. DP manufacturer also performed analytical method verification of omeprazole pellets.

<table>
<tr><td></td><td></td><td>Certificate of analysis of DS lot, batch analysis, reference/working standard and its CoA, container closure system, its specification and test methods for packing materials were provided. stability studies sheets were also provided.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 65% ± 5% RH for 12 months. DS was packed in a double polyethylene bags with desiccant placed between two bags and stored in well closed HDPE container. The DS, remained stable and within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its qualitative and quantitative composition, formulation development, manufacturing process development and in-process control, manufacturing process validation protocol and report, excipients testing methods based on pharmacopeia references with analysis reports, pharmaceutical equivalence and comparative dissolution profile, specifications and analytical procedures developed on the basis of USP monograph and its verification studies were performed, batch analysis, reference standard, container closure system and stability studies.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Losec 40mg Capsule manufactured by AstraZeneca UK which shows comparable results within specified limits.
The comparative dissolution profile was performed of the stability batch (PL001) against the Losec 40mg Capsule (Batch 3060122). Comparison was performed using 12 samples at pH 1.2 for 2 hours and at pH 6.8 for 30 min. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="2">ii.</td><td rowspan="2">Acidic buffer (pH 1.2)</td><td>120 min</td><td>6.47 %</td><td>6.05%</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="4">iii</td><td rowspan="4">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>77.39%</td><td>103.94 %</td></tr>
<tr><td>20 min</td><td>87.03%</td><td>96.72%</td></tr>
<tr><td>30 min</td><td>98.71%</td><td>96.79%</td></tr>
<tr><td colspan="3"></td></tr>
</table>
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of analytical method verification for the drug product has been provided.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
</table>

Manufacturer of API	Murli Krishna Pharma Private Limited Address: D-98, Ranjangaon MDIC, Ranjangoan, Taluka – Shirur – Pune, Maharashtra, INDIA		
API Lot No.	MKOME 017/21-22 & MKOME 022/21-22		
Description of Pack (Container closure system)	Alu-Alu blister pack (14s).		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	PL001	PL002	PL003
Batch Size	10,000 Capsules	10,000 Capsules	10,000 Capsules
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 20031925 issued by Food and Drugs Administration, Bandra, Mumbai, India valid till 06/07/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API was purchased from Murli Krishna Pharma Private Limited, India, invoice dated 30-07-2021, cleared on 17-08-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
2.	018091	TEpH 20mg Capsules Each capsules contains: - Omeprazole enteric coated pellets equivalent to Omeprazole 20mg (USP Specification)	Initial Reg. Date: 05-10-1995 Change of Brand Name: 30-04-1997 Last Renewal Submitted on: 29-07-2020 (Change of FPP Specification were also granted on 17-03-2022 from Manufacturers' specification to USP Specification) Remarks of RRR Section: Renewal application was received on 29-07-2020 i.e., within time w.r.t. date of registration.
	Name, address of Applicant / Marketing Authorization Holder		M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, Off Hub, River Road, S.I.T.E, Karachi
	Name, address of Manufacturing site.		**M/s Sami Pharmaceuticals Pvt Ltd., F -140/A, Off Hub, River Road, S.I.T.E, Karachi (DML#000938)**
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		New License
	Evidence of approval of manufacturing facility		DML issuance covering letter dated 13-09-2021 confirming Spansules (General) as formulation section
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☒Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission		Dy.No.26509 (R&I) dated 19-09-2022
	Details of fee submitted		**For transfer of registration:** PKR 150,000/- DS# 93797598901 dated on 17-08-2022
	The proposed proprietary name / brand name		**TEpH 20mg Capsules (Reg. No. 018091)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each capsule contains: Enteric coated pellets of Omeprazole equivalent to omeprazole USP …..20mg
	Pharmaceutical form of applied drug		Hard Gelatin capsule Size No. 2 having golden yellow cap and opaque body containing white to off white enteric coated pellets.
	Pharmacotherapeutic Group of (API)		Proton Pump Inhibitor
	Reference to Finished product specifications		USP Specifications

	Proposed Pack size	14's
	Proposed unit price	Already registered product
	The status in reference regulatory authorities	Losec 20mg Capsule, (EMA approved)
	For generic drugs (me-too status)	Risek 20mg Capsules, manufactured by Getz Pharma, Karachi (Reg# 019364)
	Name and address of API manufacturer.	Murli Krishna Pharma Private Limited Address: D-98, Ranjangaon MDIC, Ranjangoan, Taluka – Shirur – Pune, Maharashtra, INDIA
	1.5.11-Proposed Label	Same as already registered
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Monograph of omeprazole for DS and FPP are available in USP. Firm has summarized information of omeprazole (DS) for its nomenclature, physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer Murli Krishna is GMP certified and is responsible for all steps of manufacturing, packing and quality testing. Characterization elucidation studies was conducted using IR, NMR mass spectrum and UV absorption techniques. Potential organic impurities related to API was listed with their structure and acceptance criteria. However, during batch analysis, impurities were analyzed as per USP monograph and analysis of batch used in stability batches showed conformance to defined specifications. DS manufacturers followed in-house specification and accordingly analytical methods were developed and validated. DS lot procured was analyzed by DP manufacturer. Working standards, container closure and stability studies summaries of 03 batches were provided under Zone IV-b. Similarly, information summaries for drug product related to its description, composition, formulation development, manufacturing process, pharmaceutical equivalence and comparative dissolution profile against Losec capsules manufactured by AstraZeneca UK were provided. Development of manufacturing process and in-process controls, batch formula, DP specification based on USP specification, excipients control as per pharmacopeia reference, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided. BMR of three stability batches were also provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, Character elucidation using spectroscopy IR and NMR, physical form, polymorphism (no

<table>
<tr><td></td><td></td><td>isomerism), structure elucidation using UV, NMR, etc. were provided. Manufacturing process development, critical process steps and intermediate were identified. DS specifications were based on the inhouse method and accordingly analytical method were developed and its validating studies were performed. DP manufacturer also performed analytical method verification of omeprazole pellets. Certificate of analysis of DS lot, batch analysis, reference/working standard and its CoA, container closure system, its specification and test methods for packing materials were provided. stability studies sheets were also provided.</td></tr>
<tr><td></td><td>Stability Studies of Drug Substance (Conditions & duration of Stability studies)</td><td>Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 65% ± 5% RH for 12 months. DS was packed in a double polyethylene bags with desiccant placed between two bags and stored in well closed HDPE container. The DS, remained stable and within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its qualitative and quantitative composition, formulation development, manufacturing process development and in-process control, manufacturing process validation protocol and report, excipients testing methods based on pharmacopeia references with analysis reports, pharmaceutical equivalence and comparative dissolution profile, specifications and analytical procedures developed on the basis of USP monograph and its verification studies were performed, batch analysis, reference standard, container closure system and stability studies.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Losec 20mg Capsule manufactured by AstraZeneca UK which shows comparable results within specified limits.
The comparative dissolution profile was performed of the stability batch (PL001) against the Losec 20mg Capsule (Batch YREW). Comparison was performed using 12 samples at pH 1.2 for 2 hours and at pH 6.8 for 30 min. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="2">i.</td><td rowspan="2">Acidic buffer (pH 1.2)</td><td>120 min</td><td>5.98 %</td><td>5.74%</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td></td><td></td><td>5 min</td><td>96.80%</td><td>106.05 %</td></tr>
</table>
</td></tr>
</table>

		iii	Phosphate Buffer (pH 6.8)	10 min	104.56%	103.24%
				15 min	104.81%	104.63%
				30 min	103.53%	104.48%
	Analytical method validation/verification of product	Firm has claimed USP specifications for which report of analytical method verification for the drug product has been provided.				

STABILITY STUDY DATA			
Manufacturer of API	Murli Krishna Pharma Private Limited Address: D-98, Ranjangaon MDIC, Ranjangoan, Taluka – Shirur – Pune, Maharashtra, INDIA		
API Lot No.	MKOME 017/21-22 & MKOME 022/21-22		
Description of Pack (Container closure system)	Alu-Alu blister pack (14s).		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	PL001	PL002	PL003
Batch Size	10,000 Capsules	10,000 Capsules	10,000 Capsules
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	12-2021	12-2021	12-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 20031925 issued by Food and Drugs Administration, Bandra, Mumbai, India valid till 06/07/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API was purchased from Murli Krishna Pharma Private Limited, India, invoice dated 30-07-2021, cleared on 17-08-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.

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

Proceedings of 323rd meeting:

Registration Board deliberated that since "Spansules (General) section" is dedicated only for filling of empty hard gelatin capsules with ready to fill pellets/ granules etc., therefore, products which involve mixing before filling of pellets/granules cannot be manufactured in aforementioned facility. In this context, the Board was informed that mixing step is not involved in manufacturing of the applied products.

Decision: Registration Board decided as under:

i. **Cancelled registration of following products from the name of M/s Sami Pharmaceuticals Pvt Ltd, F-95, off Hub, River Road, S.I.T.E, Karachi (DML #000072)**

S. No.	Reg. No.	Product Name & Composition
1.	025595	TEpH 40mg Capsules Each capsules contains: - Omeprazole Enteric Coated Pellets Eq. to Omeprazole……40mg (USP Specification)
2.	018091	TEpH 20mg Capsules Each capsules contains: - Omeprazole Enteric Coated Pellets Eq. to Omeprazole……20mg (USP Specification)

ii. **Approved registration of following products in the name of M/s Sami Pharmaceuticals Pvt Ltd., Plot No. F-140/A, S.I.T.E, Karachi (DML No.000938) subject to inspection of relevant manufacturing facility.**
   a) **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
   b) **Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.**

S. No.	Product Name & Composition
1.	TEpH 40mg Capsules Each capsules contains: - Omeprazole Enteric Coated Pellets Eq. to Omeprazole……40mg (USP Specifications)
2.	TEpH 20mg Capsules

	Each capsules contains: - **Omeprazole Enteric Coated Pellets Eq. to** **Omeprazole……20mg** **(USP Specifications)**

iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.**

iv. **Before issuance of registration letter, the applicant shall submit:**

a) **Full fee of registration (for both products) for pre-registration correction/ variation in address of the registration holder from M/s Sami Pharmaceuticals Pvt Ltd., Plot No. F-140/A, off Hub, River Road, S.I.T.E, Karachi to M/s Sami Pharmaceuticals Pvt Ltd., Plot No. F-140/A, S.I.T.E, Karachi.**

b) **Valid and legalized GMP certificate of M/s Murli Krishna Pharma Private Limited, D-98, Ranjangaon MDIC, Ranjangoan, Taluka – Shirur – Pune, Maharashtra, India**

Case No.20. Request for Change in Registration Status of Products from M/s Novartis Pharma (Pakistan) Ltd, Karachi (DML No.000193) to M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) by way of Contract Manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348).

M/s. AGP Limited, D-109, S.I.T.E, Karachi has requested to change the registration status of Ternelin 4mg and 2mg Tablets from M/s Novartis Pharma Pakistan, 15-West Wharf, Dockyard Road, Karachi to M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) with permission for contract manufacturing at M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348). **The products were registered by way of contract manufacturing at M/s GSK Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro (DML No.000010) for a period of 30months.**

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of DML of M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348) w.e.f 06-02-2020.
ii. Copy of approved sections by Central Licensing Board of M/s AGP Limited, B-23-C, S.I.T.E, Karachi confirming "Tablet (general)" section (Confirmed from letter dated 30-06-2020)
iii. Copy of last GMP Inspection report dated 06-07-2022 concluding good level of GMP compliance by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348)
iv. NOC from M/s. Novartis Pharma Pakistan, 15-West Wharf, Dockyard Road, Karachi to transfer Ternelin 4mg and 2mg Tablets to M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) issued on 23-06-2022
v. Agreement of Contract manufacturing among M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) and M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348) executed in June, 2022.
vi. Relevant undertakings & commitments.

The cases were referred to QMS for evaluation. Detail of submitted documents and remarks of evaluator have been mentioned as under:

Evaluator: Mr. Asadullah (AD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	014315	Ternelin 4mg Tablets Each tablet contains:- Tizanidine HCl….4mg (USP Specification)	Initial Reg. Date: **17-10-1993** Change of Name of Registration Holder: **23-06-2007** Permission for Contract Manufacturing: **22-01-2020 (valid for 30months)**
	Name, address of Applicant / Marketing Authorization Holder		M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044)
	Name, address of Manufacturing site.		**M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348)**
	Status of the applicant		☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm		GMP Inspection report dated 06-07-2022 concluding good level of GMP compliance by M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348)
	Evidence of approval of manufacturing facility		Copy of Layout approval letter dated 02-11-2021 and renewal of DML letter dated 30-06-2020 confirming Tablet (General) among formulation section
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission		Dy.No.27320 (R&I) dated 27-09-2022
	Details of fee submitted		**For transfer of registration and contract manufacturing:** PKR 75,000/- DS# 6525105570 deposited on 05-09-2022
	The proposed proprietary name / brand name		**Ternelin 4mg Tablets (Reg. No. 014315)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each tablet contains: - Tizanidine (as hydrochloride)….4mg

	Pharmaceutical form of applied drug	Beige colored with speckled round flat tablet bisect line on one side.
	Pharmacotherapeutic Group of (API)	Skeletal Muscle Relaxant (alpha-2-adrenergic agonists)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10's
	Proposed unit price	Already registered product
	The status in reference regulatory authorities	Tizanidine Hydrochloride, EQ 4mg Base Tablet;Oral, ANDA: 076533, APOTEX (FDA)
	For generic drugs (me-too status)	Movax 4mg Tablets manufactured by M/s Sami Pharmaceutical Pvt Ltd, Karachi (Reg#042139)
	Name and address of API manufacturer.	Sun Pharmaceutical Industries Limited, Address: Plot No. 24/2, 25, Phase IV, GIDC, Panoli, Bharuch, Gujrat, India
	1.5.11-Proposed Label	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Tizanidine HCl (DS) for its physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer Sun Pharma Industries is GMP certified and is responsible for all steps of manufacturing, packing and testing. Synthesis flow, manufacturing process were briefly stated. Characterization elucidation studies was conducted using IR, UV and NMR techniques. Degradation and process related impurities and residual solvents were listed and analyzed as per USP monograph. DS manufacturers followed USP specification and accordingly analytical methods were used. DS lot procured was analyzed by DP manufacturer. Working standards, container closure and stability studies summaries of 03 batches were provided. Similarly, information summaries for drug product (Ternelin 4mg tab) related to its description, composition, choice of excipients, formulation development, manufacturing process, pharmaceutical equivalence and comparative dissolution profile against Tizanidine HCl manufactured by Teva Pharma was provided. Justification for selection of manufacturing process and in-process controls, DP specification based on USP specifications, excipients control as per pharmacopeia reference, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided.

	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, synthesis process, manufacturer and manufacturing process, character elucidation using spectroscopy IR and NMR, physical form, polymorphism (no isomerism), structure elucidation using UV, FTIR, NMR, etc. Impurities based on USP, were analysed in DS batches which remain in conformance. Analytical methods of impurities and residual solvents were developed and validated. Genotoxic impurities were also analysed. DS specifications were based on the USP monograph. Analytical method and its verification were performed. DP manufacturer also performed analytical method verification of DS. Certificate of analysis of DS lot, batch analysis, reference standard and its CoA container closure system, specification and test methods for packing materials, and stability studies sheet were provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40^{o}C ± 2^{o}C / 75% ± 5% RH for 6 months** and the long-term stability data was conducted at 25^{o}C ± 2^{o}C / 60% ± 5% RH for more than 36 months. DS was packed in a double LDPE bags (transparent followed by black) in miniature fibre board container. The DS remained stable and within specified limits as tested on defined intervals. DS manufacturer also conducted forced degradation studies in various stress condition where oxidative stress conditions leads to 9.82% and 15% degradation. DP manufacturer also conducted degradation studies of Tizanidine tablet under stress conditions including acidic, basic, oxidative, thermal and photolytic degradation for 19th months, which resolve the stability of API. Temperature data log for transportation of API were also provided.
	Module-III Drug Product:	Firm has submitted data of drug product including its qualitative and quantitative composition, formulation development, manufacturing process development and in-process control, manufacturing process validation protocol and report, excipients testing methods based on pharmacopeia references with analysis reports, pharmaceutical equivalence and comparative dissolution profile, specifications and analytical procedures developed on the basis of in-house method and its validation studies, dissolution method validation, batch analysis, justification of specifications, reference standard, container closure system and stability studies.
	Pharmaceutical Equivalence and	Pharmaceutical equivalence was performed against

<table>
<tr><td></td><td>Comparative Dissolution Profile</td><td>Tizanidine HCl 4mg Tablets (Teva Pharma, Hungary), which shows comparable results within specified limits.
The comparative dissolution profile was performed of the stability batch (TR-688) against the Tizanidine HCl 4mg Tablets (Teva Pharma, Hungary). Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 30 min. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="5">i.</td><td rowspan="5">Acidic buffer (pH 1.2)</td><td>10 min</td><td>88.8 %</td><td>79.0 %</td></tr>
<tr><td>15 min</td><td>96.1 %</td><td>95.5 %</td></tr>
<tr><td>30 min</td><td>102 %</td><td>104.2 %</td></tr>
<tr><td>45 min</td><td>100.6%</td><td>101.7 %</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="5">ii</td><td rowspan="5">Acetate buffer (pH 4.5)</td><td>10 min</td><td>72.5 %</td><td>70.7 %</td></tr>
<tr><td>15 min</td><td>90.0 %</td><td>90.2 %</td></tr>
<tr><td>30 min</td><td>98.9 %</td><td>101.2 %</td></tr>
<tr><td>45 min</td><td>101 %</td><td>101.5 %</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="4">iii</td><td rowspan="4">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>71.1 %</td><td>70.2 %</td></tr>
<tr><td>15 min</td><td>90.4 %</td><td>89.4 %</td></tr>
<tr><td>30 min</td><td>98.1 %</td><td>99.3%</td></tr>
<tr><td>45 min</td><td>99.9 %</td><td>100.6 %</td></tr>
<tr><td colspan="5">Since the dissolution were more than 85% within 15 min, f2 was not required to calculate.</td></tr>
</table></td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided.</td></tr>
</table>

STABILITY STUDY DATA

Manufacturer of API	Sun Pharmaceutical Industries Limited, Address: Plot No. 24/2, 25, Phase IV, GIDC, Panoli, Bharuch, Gujrat, India		
API Lot No.	PATZNNF010		
Description of Pack (Container closure system)	Alu-PVC blister packed, Pack Size : 1x10 tablets		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TR-687	TR-688	TR-689
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing	04-2021	04-2021	04-2021

Date			
Date of Initiation	09-04-2021	09-04-2021	09-04-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Azomax 200mg/5ml suspension, 250mg Capsules and 500mg Tablets were approved in 316th meeting of Registration Board held in March, 2022
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 22073404 issued by Food and Drugs Control Administration, Gujrat, Gandhinagar, India valid till 04/07/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	10kg of API was purchased from Sun Pharmaceutical Industries Limited, Gujrat, India invoice dated 30-11-2019, cleared on 06-12-2019 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

I	**II**	**III**	**IV**
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
2.	014316	Ternelin 2mg Tablets Each tablet contains: - Tizanidine HCl….2mg (USP Specification)	Initial Reg. Date: **17-10-1993** Change of Name of Registration Holder **23-06-2007** Permission for Contract Manufacturing **22-01-2020** **(Valid for 30months)**
	Name, address of Applicant / Marketing Authorization Holder		M/s M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044)
	Name, address of Manufacturing site.		**M/s AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348)**
	Status of the applicant		☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm		GMP Inspection report dated 06-07-2022 concluding good level of GMP compliance by M/s

		AGP Limited, B-23-C, S.I.T.E, Karachi (DML#000348)
	Evidence of approval of manufacturing facility	Copy of Layout approval letter dated 02-11-2021 and renewal of DML letter dated 30-06-2020 confirming Tablet (General) among formulation section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No.27319 (R&I) dated 27-09-2022
	Details of fee submitted	**For transfer of registration and contract manufacturing:** PKR 75,000/- DS# 3819054239 deposited on 05-09-2022
	The proposed proprietary name / brand name	**Ternelin 2mg Tablets (Reg. No. 014316)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: - Tizanidine (as hydrochloride)….2mg
	Pharmaceutical form of applied drug	Light yellow colored round flat plain on both side.
	Pharmacotherapeutic Group of (API)	Skeletal Muscle Relaxant (alpha-2-adrenergic agonists)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	10’s
	Proposed unit price	Already registered product
	The status in reference regulatory authorities	Tizanidine Hydrochloride, EQ 2mg Base Tablet; Oral, ANDA: 076533, APOTEX (FDA)
	For generic drugs (me-too status)	Movax 2mg Tablets manufactured by M/s Sami Pharmaceutical Pvt Ltd, Karachi (Reg#025594)
	Name and address of API manufacturer.	Sun Pharmaceutical Industries Limited, Address: Plot No. 24/2, 25, Phase IV, GIDC, Panoli, Bharuch, Gujrat, India
	1.5.11-Proposed Label	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of Tizanidine HCl (DS) for its physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer Sun Pharma Industries is GMP certified and is responsible for all steps of manufacturing, packing and testing. Synthesis flow, manufacturing process were briefly stated. Characterization elucidation studies was

		conducted using IR, UV and NMR techniques. Degradation and process related impurities and residual solvents were listed and analyzed as per USP monograph. DS manufacturers followed USP specification and accordingly analytical methods were used. DS lot procured was analyzed by DP manufacturer. Working standards, container closure and stability studies summaries of 03 batches were provided. Similarly, information summaries for drug product (Ternelin 4mg tab) related to its description, composition, choice of excipients, formulation development, manufacturing process, pharmaceutical equivalence and comparative dissolution profile against Tizanidine HCl manufactured by Teva Pharma was provided. Justification for selection of manufacturing process and in-process controls, DP specification based on USP specifications, excipients control as per pharmacopeia reference, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, synthesis process, manufacturer and manufacturing process, character elucidation using spectroscopy IR and NMR, physical form, polymorphism (no isomerism), structure elucidation using UV, FTIR, NMR, etc. Impurities based on USP, were analysed in DS batches which remain in conformance. Analytical methods of impurities and residual solvents were developed and validated. Genotoxic impurities were also analysed. DS specifications were based on the USP monograph. Analytical method and its verification were performed. DP manufacturer also performed analytical method verification of DS. Certificate of analysis of DS lot, batch analysis, reference standard and its CoA container closure system, specification and test methods for packing materials, and stability studies sheet were provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the long-term stability data was conducted at 25ºC ± 2ºC / 60% ± 5% RH for more than 36 months. DS was packed in a double LDPE bags (transparent followed by black) in miniature fibre board container. The DS remained stable and within specified limits as tested on defined intervals.

<table>
<tr><td></td><td></td><td>DS manufacturer also conducted forced degradation studies in various stress condition where oxidative stress conditions leads to 9.82% and 15% degradation. DP manufacturer also conducted degradation studies of Tizanidine tablet under stress conditions including acidic, basic, oxidative, thermal and photolytic degradation for 19th months, which resolve the stability of API. Temperature data log for transportation of API were also provided.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its qualitative and quantitative composition, formulation development, manufacturing process development and in-process control, manufacturing process validation protocol and report, excipients testing methods based on pharmacopeia references with analysis reports, pharmaceutical equivalence and comparative dissolution profile, specifications and analytical procedures developed on the basis of in-house method and its validation studies, dissolution method validation, batch analysis, justification of specifications, reference standard, container closure system and stability studies.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Tizanidine HCl 2mg Tablets (Teva Pharma, Hungary), which shows comparable results within specified limits.
The comparative dissolution profile was performed of the stability batch (21/066-STB/TIZ-TAB/10) against the Tizanidine HCl 2mg Tablets (Teva Pharma, Hungary). Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 30 min. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="5">i.</td><td rowspan="5">Acidic buffer (pH 1.2)</td><td>10 min</td><td>89.8 %</td><td>72.2 %</td></tr>
<tr><td>15 min</td><td>99.6 %</td><td>91.5 %</td></tr>
<tr><td>30 min</td><td>105.4%</td><td>100.5 %</td></tr>
<tr><td>45 min</td><td>105.5%</td><td>99.4 %</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="5">ii</td><td rowspan="5">Acetate buffer (pH 4.5)</td><td>10 min</td><td>85.1 %</td><td>70.9 %</td></tr>
<tr><td>15 min</td><td>100.6%</td><td>89.7 %</td></tr>
<tr><td>30 min</td><td>107.5%</td><td>98.5 %</td></tr>
<tr><td>45 min</td><td>106.8%</td><td>101.8 %</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="4">iii</td><td rowspan="4">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>83.9 %</td><td>70.2 %</td></tr>
<tr><td>15 min</td><td>98.8 %</td><td>93.9 %</td></tr>
<tr><td>30 min</td><td>101.9%</td><td>100.4%</td></tr>
<tr><td>45 min</td><td>103.9%</td><td>99.5 %</td></tr>
<tr><td colspan="5">Since the dissolution were more than 85% within 15 min, f2 was not required to calculate.</td></tr>
</table>
</td></tr>
</table>

	Analytical method validation/verification of product	Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided.

STABILITY STUDY DATA

Manufacturer of API	Sun Pharmaceutical Industries Limited, Address: Plot No. 24/2, 25, Phase IV, GIDC, Panoli, Bharuch, Gujrat, India		
API Lot No.	PATZNNF010		
Description of Pack (Container closure system)	Alu-PVC blister packed, Pack Size : 1x10 tablets		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 12 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	21/048-STB/TIZ-TAB/01	21/065-STB/TIZ-TAB/09	21/066-STB/TIZ-TAB/10
Batch Size	3000 Tablets	3000 Tablets	3000 Tablets
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	06-01-2022	06-01-2022	06-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Azomax 200mg/5ml suspension, 250mg Capsules and 500mg Tablets were approved in 316th meeting of Registration Board held in March, 2022
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 22073404 issued by Food and Drugs Control Administration, Gujrat, Gandhinagar, India valid till 04/07/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	10kg of API was purchased from Sun Pharmaceutical Industries Limited, Gujrat, India invoice dated 30-11-2019, cleared on 06-12-2019 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of	Firm has submitted record of digital data logger for temperature and humidity monitoring of

	stability chambers (real time and accelerated)	real time and accelerated stability chambers.

Decision: Registration Board decided as under:

i. **Cancelled registration of following products from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).**

S. No.	Reg. No.	Product Name & Composition
1.	014315	Ternelin 4mg Tablets Each tablet contains:- Tizanidine HCl…….……4mg (USP Specification)
2.	014316	Ternelin 2mg Tablets Each tablet contains:- Tizanidine HCl…….….2mg (USP Specification)

ii. **Approved registration of following products in the name of M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) by way of contract manufacturing at M/s AGP Limited B-23-C, S.I.T.E. Karachi (DML No. 000348).**
   a) **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
   b) **Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.**

S. No.	Product Name & Composition
1.	Ternelin 4mg Tablets Each tablet contains:- Tizanidine (as Hydrochloride)……..….4mg (USP Specifications)
2.	Ternelin 2mg Tablets Each tablet contains:- Tizanidine (as Hydrochloride)……..….2mg (USP Specifications)

iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.**

iv. **The Board noted that since instant applications for change in registration status have been submitted after expiration of previously granted permissions of contract manufacturing, therefore, fee of Rs.75000/each shall be submitted for regularization of renewal of previous registrations.**

v. **Legal opinion will be sought from Legal Affairs Division, DRAP whether cases regarding cancellation of registration from one registration holder and issuance of the same in favor of other registration holder on contract manufacturing**

basis require fee Rs.75000/- or Rs.75000/-+30000/- and registration letter will be issued accordingly

vi. **Registration Board regularized above registration and firm shall submit fee as per SRO 1005(I)/2017 before issuance of registration letter.**

Case No.21. Request for Change in Registration Status of Dermazin 1% Cream from M/s Novartis Pharma (Pakistan) Ltd, Karachi (DML No. 000193) to M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) by way of contract manufacturing at M/s. Hiranis Pharmaceutical Pvt Limited, Karachi (DML#000785).

M/s. AGP Limited, D-109, S.I.T.E, Karachi (DML No. 000044) has requested to change the registration status of Dermazin 1% Cream from M/s Novartis Pharma Pakistan, 15-West Wharf, Dockyard Road, Karachi to M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) with permission for contract manufacturing from M/s. Hiranis Pharmaceutical Pvt Limited, Plot No. E-145 to 149, North Western Industrial Zone, Port Qasim, Karachi (DML#000785). **The product was registered by way of contract manufacturing at M/s GSK Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro (DML No.000010) for a period of 30months.**

The detail of cases is as following:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of DML of M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) w.e.f 15-07-2019.
ii. Copy of approval letter for renewal of DML(dated 07-02-2014) issued by Licensing Division, confirming Cream / ointment/ Gel (General) among formulation sections.
iii. Copy of last GMP Inspection report dated 12-11-2021 concluding good level of GMP compliance by M/s. Hiranis Pharmaceutical Pvt Limited, Plot No E-145 to 149, North Western Industrial Zone, Port Qasim, Karchi (DML#000785)
iv. NOC from M/s. Novartis Pharma Pakistan, 15-West Wharf, Dockyard Road, Karachi to transfer Dermazin 1% Cream to M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) dated 05-12-2022.
v. Agreement of Contract manufacturing among M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044) and M/s Hiranis Pharmaceutical Pvt Limited, Plot No E-145 to 149, North Western Industrial Zone, Port Qasim, Karchi (DML#000785) dated 01-06-2022.
vi. Relevant undertakings & commitments.

The cases were referred to QMS for evaluation. Detail of submitted documents and remarks of evaluator have been mentioned as under:

Evaluator: Mr. Asadullah (AD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Registered Brand Name & Composition of Product**	**Registration Trail**
1.	007533	Dermazin 1% Cream Each gram contains: Silver Sulphadiazine 10mg	Initial Reg. Date: **20-08-1984** Change of Manufacturing Site and Source of Import: **14-06-2008** Transfer of Registration from Import to local: **07-11-2009**

		Change of Registration Status: **13-02-2020**
	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited, D-109, S.I.T.E, S.I.T.E, Karachi (DML#000044)
	Name, address of Manufacturing site.	**M/s Hiranis Pharmaceutical Pvt Limited, Plot No E-145 to 149, North Western Industrial Zone, Port Qasim, Karchi (DML#000785)**
	Status of the applicant	☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	GMP status of the firm	GMP Inspection report dated 12-11-2021 concluding good level of GMP compliance by M/s. Hiranis Pharmaceutical Pvt Limited, Karachi (DML#000785)
	Evidence of approval of manufacturing facility	Copy of DML issuance letter dated 07-02-2014 confirming Cream / ointment (General) among formulation section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy.No.24412 (R&I) dated 29-08-2022
	Details of fee submitted	**For transfer of registration and contract manufacturing:** PKR 75,000/- DS# 62520116489 deposited on 11-08-2022
	The proposed proprietary name / brand name	**Dermazin 1% cream (Reg. No. 007533)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: - Silver Sulphadiazine 10mg
	Pharmaceutical form of applied drug	White homogenous Cream free from lumps and foreign particles
	Pharmacotherapeutic Group of (API)	Antibacterial (Topical)
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	15gm, 25gm, 50gm, 250gm
	Proposed unit price	Already registered product
	The status in reference regulatory authorities	Silvadene 1% Cream, FDA
	For generic drugs (me-too status)	Quench 1% w/w, Ferozsons Laboratories Ltd, (Reg# 013090)

	Name and address of API manufacturer.	Srikem Laboratories Pvt Ltd, Plot No 17/24, 17/22, 17/13, 17/23, M.I.D.C, Taloja – 410 208. Navi Mumbai, Maharashtra India
	1.5.11-Proposed Label	Not submitted
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of (DS) for its physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer provided synthesis flow, manufacturing process and in process control. Characterization elucidation studies was conducted using IR and NMR techniques. The potential impurities and residual solvents were listed and their limits were defined as per USP monograph. DS manufacturers followed USP specification and accordingly analytical methods were developed and verified. DS lot used in the stability studies of finished products was analyzed by DP manufacturer. Working standards, container closure and stability studies summaries of 03 batches were provided. Similarly, information summaries for drug product related to its description, composition, choice of excipients, formulation development, manufacturing process, pharmaceutical equivalence a was provided. Justification for selection of manufacturing process and in-process controls, DP specification based on USP specifications, excipients control as per pharmacopeia reference, analytical procedure and its verification, batch analysis, reference/working standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of (DS) for its physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer Srikem Laboratories is GMP certified and is responsible for all steps of manufacturing, packing and testing. Synthesis flow, manufacturing process and in process control were briefly stated. Characterization elucidation studies was conducted using IR and NMR techniques. The potential impurities and residual solvents were listed and their limits were defined as per USP monograph. DS manufacturers followed USP specification and accordingly analytical methods were developed and verified. DP manufacturer also verified the analytical method for silver sulphadiazine. CoA of three batches produced in 2021 were provided. DS lot used in the stability studies of finished products was analyzed by DP manufacturer. DS manufacturer developed working standards against USP reference

		standard and provided its COA. Container closure system used for DS was analyzed and their CoA were provided. Stability studies summaries of 03 batches manufactured in 2019 were provided at accelerated and real time conditions as per Zone IV-A.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of drug substance at both accelerated as well as real time conditions**. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months** and the long-term stability data was conducted at 30ºC ± 2ºC / 60% ± 5% RH for 18 months. DS was packed in LDPE bags placed in HDPE containers. The DS remained stable and within specified limits as tested on defined intervals.
	Module-III Drug Product:	Firm has submitted data of drug product including its qualitative and quantitative composition of 1% w/w cream of silver sulphadiazine. Product was developed with reference product formulation developed by Novartis Pharma Pakistan using similar excipients. Manufacturing process development, critical attributes, and process validation protocol were provided. Excipients specification were provided which mostly based on pharmacopeial references. Pharmaceutical equivalence was performed against the Quench 1 % cream, manufactured by Ferozsons Laboratories. DP follows USP specifications and analytical procedures were verified. Batch analysis of three batches revealed conformance to assigned specifications. Working standard used in analytical studies was provided by the DS manufacturer. Plastic laminated tube with inner aluminium layer were used as container closure system were used and its CoA was provided.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical equivalence was performed against Quench 1% cream (Ferzosons Laboratories Pvt Ltd), which shows comparable results within specified limits.
	Analytical method validation/verification of product	Firm has claimed USP specifications for which report of verification of analytical method for the drug product has been provided. Analytical method for silver sulphadiazine, and methyl parben & propyl paraben were verified.

STABILITY STUDY DATA	
Manufacturer of API	Srikem Laboratories Pvt Ltd, Plot No 17/24, 17/22, 17/13, 17/23, M.I.D.C, Taloja – 410 208. Navi Mumbai, Maharashtra India
API Lot No.	214001010
Description of Pack	Plastic laminated tube with inner aluminium layer packed in unit cartoon (1s;50G)

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 12 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	TF-201021	TF-211021	TF-221021
Batch Size	1Kg	1Kg	1Kg
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	24-10-2021	24-10-2021	24-10-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 6100336 issued by Food and Drugs Control Administration, Maharashtra state, India valid till 11/03/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	13.5kg of API was purchased from Srikem Laboratories Pvt Ltd, India, invoice dated 07-04-2021, cleared on 15-06-2021 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s Novartis Pharma (Pakistan) Limited, 15- West Wharf, Dockyard Road, Karachi (DML No. 000193).

S. No.	Reg. No.	Product Name & Composition

1.	**007533**	**Dermazin 1% Cream** **Each gram contains:** **Silver Sulphadiazine…….. 10mg**

ii. Approved registration of following products in the name of M/s AGP Limited, D-109, S.I.T.E, Karachi (DML#000044) by way of contract manufacturing at M/s. Hiranis Pharmaceutical Pvt Limited, Plot No. E-145 to 149, North Western Industrial Zone, Port Qasim, Karachi (DML#000785).

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

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

S. No.	Product Name & Composition
1.	**Dermazin 1% Cream** **Each gram contains:** **Silver Sulphadiazine…….. 10mg** **(USP Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP) without waiting for confirmation of minutes of instant meeting.

iv. Legal opinion will be sought from Legal Affairs Division, DRAP whether cases regarding cancellation of registration from one registration holder and issuance of the same in favor of other registration holder on contract manufacturing basis require fee Rs.75000/- or Rs.75000/-+30000/- and registration letter will be issued accordingly.

v. Registration Board regularized above registration and firm shall submit fee as per SRO 1005(I)/2017 before issuance of registration letter.

Case No.22. Recommendation to Registration Board in the Light of Decision of Pharmacovigilance Risk Assessment Expert Committee.

Division of Pharmacy Services, DRAP has informed that first meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) was held on 12th October, 2022. The committee discussed two cases of local signals and eight cases of reliance on international agencies. Accordingly, safety-related decisions were made along with following recommendations to Registration Board:

I. <u>DOMESTIC SIGNALS</u>

1. *Anaphylactic Reaction with Diclofenac Sodium.*

<u>Decision of PRAEC:</u>

i. The PRAEC after detailed deliberation and discussion decided to update the warning, precaution & contraindication sections of the prescribing information/ safety specification/ label of Diclofenac Sodium injection about the occurrence of anaphylactic reaction/ anaphylactic shock and its contraindication in a patient with a history of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.

ii. *Furthermore, the PRAEC in light of Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022 decided to recommend the Registration Board to update the safety specification/ label of Diclofenac Sodium Injection.*

2. Infusion-related hypersensitivity reactions with Remdesivir.

Decision of PRAEC

The PRAEC after detailed deliberation & discussion and in light of recommendations of the National Pharmacovigilance Centre decided as under:

i. *To update the prescribing information/ safety specification/ label of Remdesivir with the inclusion of information related to infusion-related hypersensitivity reactions and its monitoring in the warning and precaution sections and onward recommendation to the Registration Board in light of Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022. Furthermore, all the registration holders should also introduce educational training for healthcare professionals on proper preparation, administration and flow rate of Remdesivir, and monitoring of patients;*
ii. *To advise the Registration Board to review the grant of Emergency Use Authorization for the product Viso-Rem Solution for infusion in light of the investigation carried out by the panel of QA and LT Division of the DRAP; and*
iii. *Furthermore, to advise the QA and LT Division of the DRAP in light of Rule 10 (1) (e) of the Pharmacovigilance Rules, 2022 to strengthen its surveillance mechanism of registration holders of Remdesivir.*

II. RELIANCE OF INTERNATIONAL SAFETY DECISIONS.

1. Clozapine: Risk of serious bowel complications

Decision of PRAEC

i. *The PRAEC after detailed deliberation and discussion decided to update and strengthen the warning section of Clozapine with gastrointestinal side effects, including constipation and severe bowel problem in light of Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022.*
ii. *It was decided to onward recommend/inform the Registration Board for necessary action in the matter.*

2. Iodinated contrast media (ICM) injections: Risk of Hypothyroidism in babies and young children.

Decision of PRAEC

i. *The PRAEC after detailed deliberation and discussion decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update the warning and precaution section of the prescribing information of the entire class of iodinated contrast media (ICM) that are used for radiological purposes to include risks of an underactive thyroid or a temporary decrease in thyroid hormone levels in children 3 years or younger i.e newborns, particularly those born premature, and children in their first 3 years with underlying conditions such as heart issues etc*
ii. *It was decided to onward recommend/inform the Registration Board for necessary action in the matter.*

3. Remdesivir: Risk of sinus bradycardia

Decision of PRAEC

i. *The PRAEC after discussion decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update the prescribing information (warning & adverse drug reactions sections) of Remdesivir to include the potential risk of sinus bradycardia.*
ii. *It was decided to onward recommend/inform the Registration Board for necessary action in the matter.*

4. Atezolizumab: Risk of severe cutaneous adverse reactions (SCARs)

Decision of PRAEC

i. *The PRAEC after deliberation decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update prescribing information of Atezolizumab (Tecentriq®) to include*

the risk of severe cutaneous adverse reactions (SCAR) including Stevens-Johnsons Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN).

ii. *Furthermore, it was decided that registration holders should issue direct healthcare professional communication in this regard.*

iii. *It was decided to onward recommend/inform the Registration Board for necessary action in the matter.*

5. Metformin and reduced vitamin B12 levels

Decision of PRAEC

i. *The PRAEC after discussion decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update prescribing information of Metformin and other medicines containing Metformin to state that vitamin B12 deficiency is an adverse drug reaction with Metformin use and the risk of this adverse reaction occurrence increases with increasing metformin dose and treatment duration and in patients with risk factors known to cause vitamin B12 deficiency.*

ii. *It was decided to onward recommend/inform the Registration Board for necessary action in the matter.*

6. Pregabalin: Risk of Major Congenital Malformations

Decision of PRAEC

i. *The PRAEC after detailed deliberation and discussion decided as per Rule 10 (1) (h) (iv) and (vi) of Pharmacovigilance Rules, 2022 to update prescribing information of Pregabalin to include information from a new study that pregabalin may slightly increase the risk of major congenital malformations if used in pregnancy and include advise on effective contraception during treatment in pregnancy.*

ii. *It was decided to onward recommend/inform the Registration Board for necessary action in the matter*

7. Interaction between hydroxychloroquine or chloroquine, and macrolide antibiotics: increased risk of cardiovascular events with co-administration.

Decision of PRAEC

i. *The PRAEC after discussion decided as per Rule 10 (1) (h) (iv) and (vi) of Pharmacovigilance Rules, 2022 to update prescribing information (warning and interaction sections) of hydroxychloroquine, chloroquine and macrolide antibiotics (azithromycin, erythromycin or clarithromycin excluding topical macrolides) about the potential interaction of increased risk of cardiovascular events and cardiovascular mortality if hydroxychloroquine or chloroquine is taken with a macrolide-antibiotic.*

ii. *It was decided to onward recommend/inform the Registration Board for necessary action in the matter.*

8. Hydroxyethyl-starch solutions for infusion: risk of kidney injury and death

Decision of PRAEC

The PRAEC after detailed deliberation and discussion and as per Rule 10 (1) (h) (v) of Pharmacovigilance Rules, 2022 decided to recommend to the Registration Board to suspend the registration of Hydroxyethyl-Starch (HES) solutions in Pakistan subject to the availability of alternative treatment options.

Decision: Registration Board deferred the case for further deliberation in collaboration with Pharmacy Services Division, DRAP.

Case No.23. Request for Change in Registration Status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro Along-with End to End Local Manufacturing.

Registration Board in its 317th meeting held on 16th-17th May, 2022 considered the request of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro for change in registration status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name.

The applicant initially applied for change in registration status from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name along-with end to end local manufacturing (Dy.No.33338/R&I dated 21-12-2021). However, the firm vide their letter No.REF/DRAP/Reg-003/0322 received dated10-03-2022 (Dy.No.6669) revised their request by informing that there is no change in manufacturing site (abroad) and repacking site (local).

Decision of M-317:

Registration Board deferred the case for submission of updated approval status of the applied formulation along-with safety and efficacy profile in reference regulatory authorities adopted by the Board in its 275th meeting. Moreover, the Board further advised to submit valid and legalized CoPP of the product as existing has been expired.

In line with the above-mentioned decision of Registration Board following information has been collected regarding risk-benefit profile of Paracetamol MR Tablet and regulatory steps taken by different reference regulatory authorities in the best interest of patients.
[Reference: Application to amend the Poisons Standard - Modified Release Paracetamol (tga.gov.au) accessed dated 04-11-2022]:

Paracetamol Modified Release Tablet:

Paracetamol MR tablets are constructed in two layers, an IR layer (31%) and a SR layer (69%) that gradually releases paracetamol over a period of 8 hours at normal doses.
The highest recommended dose of paracetamol for adults is 1.3 g and the maximum daily dose is 4 g (i.e., 2 tablets 3 times a day with highest dose of 6 tablets a day). A toxic dose is 10g or 200mg/kg (whichever is greater). The majority of patients who overdose take less than 30 g.

Summary of Benefits of MR Paracetamol:

i. Three times daily dosing and reduction of tablet burden (compared with four times daily dosing of IR formulations);
ii. MR paracetamol may be preferred over IR paracetamol for long term use in patients with chronic pain conditions such as osteoarthritis.

Summary of Risks of MR paracetamol:

i. Unpredictable and undefined pharmacokinetic profile following an overdose with MR paracetamol.
ii. Severe consequences of overdose may be more likely to occur in patients who have ingested MR paracetamol;
    a. High potential for treating clinician to not be aware that a patient has ingested MR paracetamol
    b. Unpredictable pharmacokinetic profile making monitoring and treatment difficult
iii. Current best practice guidelines do not completely address MR toxicity.
iv. Chronic supratherapeutic overdose is also thought to be not uncommon. This is likely largely due to confusion about the difference in dose between MR and IR paracetamol with the maximum dose being 6 tablets per day for the MR formulation rather than 8 tablets per day for IR. This confusion may be contributed to by the products being available adjacent to one another OTC without counselling/education provided at the point of sale.
v. Paracetamol overdose can result in liver failure requiring liver transplant and may be fatal if not treated appropriately in a timely manner.

To overcome the risk associated with overdosing of Paracetamol MR Tablet, following different regulatory actions have been taken by EMA and TGA:

A. **European Medicines Agency (EMA)** on recommendations of Pharmacovigilance Risk Assessment Committee (PRAC) suspended the marketing of MR paracetamol formulations in September 2017 as the **advantages of a longer-acting product did not outweigh the complications of managing an overdose of the medicine**, since the treatment procedures for immediate-release products are not appropriate for modified-release paracetamol.

In many cases, it may not be known whether an overdose of paracetamol involves immediate-release or modified release products, making it difficult to decide how the overdose should be managed.

Furthermore, the **medicines will remain suspended unless the companies that hold the marketing authorizations can provide evidence of appropriate and practical EU-wide measures to help prevent overdose with these products and adequately reduce its risks.**

B. Therapeutic Goods Administration (TGA) Australia has up-scheduled MR paracetamol from ***Schedule 2 'Pharmacy Medicine'*** to ***Schedule 3 'Pharmacist Only'*** in order to ensure appropriate patient counselling on correct dosing and the risks associated with overdose, whether intentional or accidental.

- There are well established guidelines in Australia for the management of paracetamol overdose including with MR paracetamol.
- The treatment of paracetamol overdose is dependent on a number of factors and treatment given will vary accordingly. Key parameters include dose taken and time since exposure, if known.
- The mainstay of treatment is with acetylcysteine. Whether acetylcysteine is administered depends on certain clinical parameters, including the use of the paracetamol treatment nomogram which plots the blood paracetamol concentration against time.
- Other investigations include measurement of liver function to assess for liver toxicity.

Approval status of Paracetamol extended-release tablets in different regulatory authorities is as under:

S/N	Country	Authority	Product	Approval status
1.	Australia	TGA (Therapeutic Goods Administration) PANADOL OSTEO (reformulation) paracetamol 665 mg modified release tablet blister pack (260264) | Therapeutic Goods Administration (TGA)	PANADOL OSTEO paracetamol 665mg modified release tablet of M/s GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	Active (Non-prescription medicine) **(Pharmacist Only Medicine)**
2.	Australia	TGA (Therapeutic Goods Administration) PANADOL BACK & NECK LONG LASTING paracetamol 665mg modified release tablets blister pack (78493) | Therapeutic Goods Administration (TGA)	PANADOL BACK & NECK LONG LASTING paracetamol 665mg modified release tablets of M/s GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	Active (Non-prescription medicine) **(Pharmacist Only Medicine)**
3.	USA	US FDA Drugs@FDA: FDA-Approved Drugs	Acetaminophen 650mg extended release tablet	Active (Human OTC drug)
4.	Canada	Health Canada Search results summary (canada.ca)	ARTHRITIS PAIN EXTENDED RELIEF tablet 650mg (Paracetamol extended release tablet)	Approved.

5.	Finland	The Finnish Medicines Agency (Fimea) Drug search - Fimea	Panadol Extend 665mg modified release tablets of M/s GlaxoSmithKline Consumer Healthcare APS	Marketed.
6.	Denmark	Danish Medicine Agency Search - Summary of Product Characteristics (produktresume.dk)	Panodil, Modified Release Tablets 665mg of M/s GlaxoSmithKline Consumer Healthcare APS	Marketed.

List of Countries (Other than RRAs) where Paracetamol MR Tablet has been reported to be available	
i.	New Zealand **(Pharmacist Only Medicine)**
ii.	Singapore
iii.	Hong Kong
iv.	Malaysia
v.	UAE
vi.	Lebanon
vii.	Oman
viii.	Qatar
ix.	Bahrain
x.	Jordan
xi.	Kuwait
xii.	Egypt
xiii.	Saudi Arabia

Approval Status of Paracetamol MR tablets in Pakistan:

Application for registration of Panadol Extend Tablet (containing Paracetamol 665mg in modified release form) for finished import from Australia was received dated 22.06.2012 from M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi and initially considered by the Registration Board in its 243rd meeting held on 08th – 09th May, 2014. Later on, the firm revised the application from 'finished import' to 'bulk import and local repacking'. Registration Board in its 289th meeting held on 14th – 16th May, 2019 approved registration of aforementioned product such that the tablets will be imported in bulk from M/s GlaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia and will be blistered and packed along-with final quality control release of the finished pharmaceutical product at M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi. The approval was granted on following grounds:

- Evidence of approval of applied formulation by the reference regulatory authority i.e., Therapeutic Goods Administration (TGA), Australia and confirmation of free sale status in Australia as determined from submitted legalized Certificate of Pharmaceutical Product (CoPP) for bulk labeled tablets.
- On-site Investigation by a panel comprising of Dr. Saif ur Rehman Khattak (Director, CDL, DRAP, Karachi), Dr. Najam us Saqib (Additional Director, DRAP, Karachi) and Mr. Kirshan Das (Assistant Director, DRAP, Karachi) for confirmation of Authenticity / Genuineness of stability data in final container closure system performed by M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi.

Reg. No.	**Product Name & Composition**	**Registration Trail**
097070	Panadol Extend Tablet	**Initial Reg. Date:** 08-07-2019

	Each modified release tablet contains: Paracetamol……665 mg (USP Specifications) Bulk Import & Local Repacking	**Change of Source of Bulk Tablets dated 12- 03-2021:** From M/s GlaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia to M/s Glaxo Welcome, S.A. Avda. Extremadura, 3, Pol. Ind. Allendeduero, Arvanda de Duero, 09400 Burgos, Spain **Change of Local Repacking Site dated 26- 10-2021**: From M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro
Information printed on label regarding management of Overdose:		In case of overdose, immediate medical management is required by visiting nearest Emergency Medical Center, even if symptoms of overdose do not appear.

Current Application:

M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro has now requested for change in registration status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name along-with **end to end local manufacturing**. The product is currently registered for bulk import (of tablets) from Glaxo Welcome Spain and local repacking along-with quality control release at M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro.

Evaluation report will be placed before the Registration Board during the meeting.

Decision: Registration Board deferred the case for following reasons:

iii. **Evaluation of application submitted for change in registration status of Panadol Extend Tablet 665mg (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro along-with end to end local manufacturing.**

iv. **The applicant shall submit detail of measures adopted by other countries (whether RRA or non-RRA) to mitigate the risk as reported by EMA.**

v. **The applicant shall also submit detail of practicable measures which will be adopted after grant of marketing authorization to prevent the risk of toxicity associated with over-dose of above-mentioned product.**

Registration-II Section

Case No. 01 M/s. Saffron Pharmaceuticals (Pvt.) Ltd; 19 Km, Sheikhupura Road, Faisalabad

M/s. Saffron Pharmaceuticals (Pvt.) Ltd; 19 Km, Sheikhupura Road, Faisalabad were granted registration of following products with MRP demanded by the firm as mentioned in the minutes. However, the firm has submitted a request that these MRPs are not viable for manufacturing and they unable to manage the cost. Same case was placed in 2nd meeting of C&P Division & PE&R Division and it was decided in said meeting that "The MRPs were granted to firm as per their demand, hence the request of the firm cannot be acceded for revision in MRP, firm may approach C&P Division". The detail is given below:-

S. No.	Reg. No. & Date	Name of Drug(s) with composition	Existing MRP & Pack size
1.	057446 29-04-2009	Dystrone Tablet Each tablet contains:- Dydrogesterone …… 10mg	Rs.25/20's

		(BP Specifications)	
2.	081383 27-07-2016	Episaf 250mg Tablet Each film coated tablet contains:- Levetiracetam …… 250mg (USP Specifications)	Rs.40/1x10's

Later on, firm has submitted fresh applications for product Episaf 250mg Tablet in 293rd meeting and registration letter has also been issued with following details

S. No.	Reg. No. & Date	Name of Drug(s) with composition	Existing MRP & Pack size
1.	102374 29-04-2020	Episaf 250mg Tablet Each film coated tablet contains:- Levetiracetam …… 250mg (USP Specifications)	Rs.787.00 / 30s

For product Dystrone 10mg Tablet, firm has also submitted fresh application which was approved in 313th meeting but registration letter was not yet issued as it was revealed during scrutiny of record that firm has already been granted registration of said product as mentioned above.

Now firm has applied for correction in MRP of Dystrone 10mg Tablet (Reg. No. 057446) as per of C&P Division's letter No. F. 11-12/2021-DD (P) dated 25-06-2021 regarding "Clarification with respect to issuance of revised MRP where the applicant/ pharmaceutical concern had demanded lower MRPs at the time of submission of application for registration" clarified as under;

> The matter was placed before Drug Pricing Committee (DPC) in its 48th meeting held on 03-06-2021 and DPC after considering statutory construction of law, provisions of Drug Pricing Policy-2018 and facts, decided as under;
>
> ***"MRPs of generics are fixed with prospective effect on uniform basis under Drug Pricing Policy- 2018 without regard to a particular brand or applicant. Therefore, all applicants whose registration letters are issued under sub-rule (4) of rule 29 of the Drugs (Licensing, Registration and Advertising) Rules, 1976 after notification of MRPs are entitled for notified MRPs. If a lower MRP is issued to any applicant on the basis of an initial demanded MRP, it will create anomalies against provision of paragraph 12(5) of the Drug Pricing Policy-2018. Therefore, applicants be issued with SRO notified MRPs instead of initial demanded prices. Moreover, corrigendum be issued to applicant companies if initial demanded MRP was notified in registration letter instead of SRO notified MRP under section 12 of the Drugs Act,1976 after approval by the Federal Government.".***

Decision of 320th meeting of RB.

> **Registration Board decided to issue show cause notice to M/s. Saffron Pharmaceuticals (Pvt.) Ltd., Faisalabad for cancellation of Episaf 250mg Tablet (Reg. No. 102374). The Board further decided that registration letter shall not be issued for product Dystrone 10mg Tablet approved in 313th meeting as firm already holds registration of same product.**

In view of above decision of Registration Board, show-cause notice has been served to M/s. Saffron Pharmaceuticals (Pvt.) Ltd., Faisalabad and reply of firm is as under:

They have withdrawn the registration of Episaf 250mg Tablet (Levetiracetam) Reg. No. 081383 and submitted copy of request submitted vide letter Ref. #: Saf/020/076 dated 04-05-2020. They have also not applied for the renewal so; they are not entitled / hold the registration. They had many times applied for correction in price but corrigendum of old registration Episaf 250mg Tablet was not issued. They have not manufactured a single batch of this product due to price issue from registration date 26-07-2016. Renewal of Episaf 250mg Tablet Reg. No. 081383 was expired on 27-07-2021. They have requested to allow firm to retain registration of Episaf 250mg Tablet Reg. No. 102374 and cancel the registration of Episaf 250mg Tablet Reg. No. 081383

They have further submitted that They have not manufactured Dystron 10mg Tablet (Dydrogesterone) Reg. No. 057446 due to price issue from date of registration date 29-04-2009. Updated renewal of this product is also not clear. They had applied for corrigendum which was also

not issued. Hence, they applied new dossier with new fee which was approved in 313th meeting. They have requested to issue updated price corrigendum of Dystron 10mg Tablet (Dydrogesterone) Reg. No. 057446 or issue new registration letter of Dystron 10mg Tablet approved in 313th meeting.

Decision: Registration Board deliberated on reply of M/s. Saffron Pharmaceuticals (Pvt.) Ltd; 19 Km, Sheikhupura Road, Faisalabad in response to show cause dated 27-10-2022 w.r.t. cancellation of registration of Episaf 250mg Tablet (Reg. No. 102374) and decided to confirm renewal status of Episaf 250mg Tablet (Reg. No. 081383) from RRR section and verification of withdrawal letter from R &I for further deliberation in forthcoming meeting.

Case No. 02 M/s. Rogen Pharmaceuticals Plot No. 30 S-4 National Industrial Zone Rawat Islamabad

Registration Board in its 237th meeting considered the following application of M/s. Rogen Pharmaceuticals Plot No. 30 S-4 National Industrial Zone Rawat Islamabad by way of contract manufacturing from M/s Caraway Pharmaceuticals Islamabad and decided as mentioned against each. Detail is as under:-

Sr. No.	Name of Drug(s)	Demanded Pack Size/Price	Decision of 237th meeting of RB	Remarks
1.	Lear 1gm Injection Each vial contains:- A sterile mixture of 500mg Cefoperazone Sodium (as Cefoperazone Sodium USP) and 500mg Sulbactam Sodium (as Sulbactam sodium USP) (Anti-Infectives: Beta Lactamase Inhibitor/Cephalosporin)	As Per SRO As Per SRO	The Contract Manufacturing Policy is under consideration by policy Board so the application should be deferred till finalization of the same.	Firm has submitted application for change of contract manufacturer from M/s. Caraway to M/s. Seraph vide dy. No. 34532 dated 17-10-2018.
2.	Lear 2gm Injection Each vial contains:- A sterile mixture of 1000mg Cefoperazone sodium (as Cefoperazone Sodium USP) and 1000mg Sulbactam Sodium (as Sulbactam Sodium USP) (Anti-infective: Beta Lactamase Inhibitor/Cephalosporin)	As Per SRO As Per SRO	-do-	Firm has submitted application for change of contract manufacturer from M/s. Caraway to M/s. Seraph vide dy. No. 34533 dated 17-10-2018. Revised form-5 contains strength as follows: Each vial contains: Cefoperazone as Sodium…….250mg Sulbactam as Sodium…….250mg while in rest of application, strength is correct.
3.	Elkin Injection 1gm Each vial contains:- Cefipime HCl (USP)… 1000mg (Anti-Infectives / Cephalosporin)	As Per SRO As Per SRO	-do-	Firm has submitted application for change of contract manufacturer from M/s. Caraway to M/s. Seraph vide dy. No. 34531 dated 17-10-2018. Label claim as per RRA is as under: **"Each vial contains:-**

				Cefipime HCl …1000mg (With L-Arginine)"
4.	Elkin Injection 500mg Each vial contains:- Cefipime HCl (USP)…… 500mg (Anti-Infectives / Cephalosporin)	As Per SRO As Per SRO	-do-	Firm has submitted application for change of contract manufacturer from M/s. Caraway to M/s. Seraph vide dy. No. 34530 dated 17-10-2018. Label claim as per RRA is as under: **"Each vial contains:- Cefipime HCl …500mg (With L-Arginine)"**

Firm has submitted following documents:

i. Initial registration application (Original) with fee of Rs.8000/- dated 27-05-2010 and Rs.42000/- dated 03-05-2016 for each product.
ii. Form 5 dated 17.10.2018
iii. Fresh fee of Rs.75000/- each, verified from website, for change of contract manufacturer from M/s. Shawan to M/s. Seraph.
iv. Contract agreement between M/s. Rogen Pharmaceuticals Plot No. 30 S-4 National Industrial Zone Rawat Islamabad and M/s. Seraph Pharmaceutical Plot No.210, Industrial Triangle, Kahuta Road, Islamabad dated 27-06-2018.
v. GMP Inspection report of M/s. Rogen Pharmaceuticals, Islamabad dated 06-06-2022 with conclusion that firm is operating satisfactory level of cGMP.
vi. Panel Inspection report dated 11-10-2022 having evaluation of the inspection report as Good.

Decision: Registration Board approved above products at Sr. No. 01-04 in the name of M/s. Rogen Pharmaceuticals Plot No. 30 S-4 National Industrial Zone Rawat Islamabad by way of contract manufacturing form M/s. Seraph Pharmaceutical Plot No.210, Industrial Triangle, Kahuta Road, Islamabad.

Case No.03: Registration of Drugs of M/s. Citi Pharma, Lahore Formerly M/s. Askari Pharma, Lahore.

Registration Board in its 211th meeting approved following products in the name of M/s. Askari Pharma, Lahore but registration letters were not issued to the firm. Now title of the firm has been changed to M/s. Citi Pharma (Pvt) Ltd., Lahore and firm has requested for issuance registration letter. Details are as under;

Sr. No.	Name of Drug(s) & Composition	Demanded Pack Size & MRP	Decision of Board Meeting M-211	Remarks
1.	Proask 200mg Tablets. Each Tablet Contains:- Ibuprofen……200mg	50x10's Rs.387.40	**Approved subject to the verification of the HVAC system of the firm.**	i. Approved in MHRA as film coated tablet. **Firm has submitted revised Form-5 with film coated tablet without submission of fee.** ii. Product is available in USP
2.	Proask 400mg Tablets. Each Tablet Contains:- Ibuprofen……400mg	25x10's Rs.387.40	**-do**	i. Approved in MHRA as film coated tablet. **Firm has submitted revised Form-5 with film coated tablet without submission of fee.** ii. Product is available in USP
3.	Proask 600mg Tablets. Each Tablet Contains:-	600's	**-do-**	i. Approved in MHRA as film coated tablet. **Firm has**

	Ibuprofen……600mg	Rs. 1536.15		**submitted revised Form-5 with film coated tablet without submission of fee.** ii. Product is available in USP

Firm has submitted following documents;

i. Form-5.

ii. No evidence of fee submission of Rs.8000/- & Rs.12000/-. However, firm has submitted fee of Rs.30,000/- each for change of title of firm from M/s. Askari Pharma to M/s. Citi Pharma

iii. GMP certificate based upon evaluation conducted on 19-03-2019.

iv. DML renewal inspection report dated 19-03-2019 which confirmed installation of HVAC system.

Registration Board in 308th meeting deferred the products for submission of revised formulation as per RRA / Innovator product.

Now firm has submitted fee of Rs.7500/- each for correction in coating from uncoated tablet to film coated tablet. Firm has also submitted fee of Rs.20000/- each as initial registration fee.

Decision: Registration Board approved above products at Sr. No. 01-03 in the name of M/s. Citi Pharma (Pvt) Ltd. 3-Km Head Baloki Road Phool Nagar Kasur.

Case No.04 Correction in Minutes of Registration Board Meetings.

i. M/s Rotex Pharma (Pvt) Ltd. Plot No. 206-207 Industrial Triangle Khuta Road Islamabad

Registration Board in its 295th meeting approved following product of M/s. Rotex Pharma (Pvt) Ltd. Plot No. 206-207 Industrial Triangle Khuta Road Islamabad. Registration letter was not issued as there is some typo error in strength of formulation. Detail is as under;

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition	Remarks
1.	Hemorox 150mg Capsule Each Capsule Contains: Iron Polysaccharide Complex Eq. to Elemental Iron…50mg Manufacturer specifications	Hemorox 150mg Capsule Each Capsule Contains: Iron Polysaccharide Complex Eq. to Elemental Iron…150mg Manufacturer specifications	Registration letter not yet issued.

Firm had submitted receiving of registration application and yellow copy of fee challan which reveals that applied strength is 150mg instead of 50mg.

Decision: Registration Board decided to approve the correction in above product with following details.

"Hemorox 150mg Capsule
Each Capsule Contains:
Iron Polysaccharide Complex Eq. to Elemental Iron…150mg"

ii. M/s Linear Pharma Plot No. 18 S. No. S-4 National Industrial Zone (RCCI) Rawat.

Registration Board in its 263rd meeting approved following product of Linear Pharma Plot No. 18 S. No. S-4 National Industrial Zone (RCCI) Rawat . Registration letter was not issued as there is some typo error in strength of formulation. Detail is as under;

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition	Remarks
1.	Xylo liquid vial Injection 10% Each 50ml contains: Lidocaine HCl…….500mg	Xylo liquid vial Injection 10% Each 50ml contains: Lidocaine HCl…….5000mg	Registration letter not yet issued

Firm had submitted receiving of registration application and yellow copy of fee challan which reveals that applied strength is 5000mg instead of 500mg.

Decision: Registration Board deferred the request of the firm for submission of approval of product in reference regulatory authorities along with generic status.

iii. M/s. McOlson Research Laboratories (Pvt) Ltd. 26-Km Lahore Sharakpur Road District Sheikhupura

Registration Board in its 290th meeting approved following product of M/s. McOlson Research Laboratories (Pvt) Ltd. 26-Km Lahore Sharakpur Road District Sheikhupura. Detail is as under:

Sr. No.	Reg. No.	Name of Approved Drug(s) & Composition
1.	099527	Quis 100mg/5ml Dry Suspension Each 5ml after reconstitution Contains: Linezolid……100mg

Firm was issued registration letter vide letter No. F .5-3/2019-Reg-II (M-290) dated 30-10-2019. Firm has submitted that they had applied above product by way contract manufacturing from M/s. Jenner Pharmaceuticals (Pvt) Ltd. Plot No. 2, M-2 Pharma Zone 28-Km Lahore Sharaqurpur Road District Sheikhupura while it was not mentioned in registration letter. While in minutes it was mentioned as self-manufactured product and registration letter was also issued accordingly.

Firm has submitted copy of receiving of registration application on which it is mentioned that "this product will be manufactured by M/s. Jenner Pharmaceuticals (Pvt) Ltd. Plot No. 2, M-2 Pharma Zone 28-Km Lahore Sharaqurpur Road District Sheikhupura" while fee endorsement by statistical officer on receiving of application is of Rs.20000/-. Firm has also submitted copy fee challan of Rs.50000/- while endorsement by statistical officer is also Rs.20000/- instead of Rs.50000/-.

Decision: Registration Board approved correction in manufacturer of Quis 100mg/5ml Dry Suspension as per following detail:

Reg. No.	Product Name & Composition	Registration Holder	Contract Manufacturer
099527	**Quis 100mg/5ml Dry Suspension Each 5ml after reconstitution Contains: Linezolid……100mg**	**M/s. McOlson Research Laboratories (Pvt) Ltd. 26-Km Lahore Sharakpur Road District Sheikhupura. (DML No. 000664)**	**Jenner Pharmaceuticals (Pvt) Ltd. Plot No. 2, M-2 Pharma Zone 28-Km Lahore Sharaqurpur Road District Sheikhupura (DML No. 000823)**

- **Registration Board further decided that fee challan endorsement shall be verified from budget and Accounts Division.**

Case. No.05 Standardization/Correction of Label Claim as Per Reference / Innovator Product.

i. M/s Winlet Pharmaceutical, 30-km, Lakisa Lahore-Sargodha road, Sargodha

Registration Board in its 295th approved following product of M/s Winlet Pharmaceutical, 30-km, Lakisa Lahore-Sargodha road, Sargodha. Firm has submitted request for standardization of label claim as per reference product Ketosteril Tablets approved in Germany. Firm has also submitted fee of Rs.30,000/-. Detail is as under:

Sr. No.	Name of Drug(s) & Composition	Label claim as per RRA (Germany)
1.	Amilet Tablet Each Film Coated Tablet Contains: L-Isoleucin…67mg L-Leucin…101mg L-Phenylanaline…68mg L-Valine……86mg L-Methionine…59mg	**Each film-coated tablet contains: α-keto analogue of isoleucine, calcium salt…… 67mg α-keto analogue of leucine, calcium salt … 101mg α-keto analogue of phenylalanine, calcium salt…68mg α-keto analogue of valine, calcium salt…….. 86mg**

	Lysine Acetate……105mg L-Threonine…53mg L-Tryptophan…23mg L-Histidine…38mg L-Tyrosine…30mg	**α-Hydroxy analogue of methionine, calcium salt…59mg** **Lysine acetate 105mg corresponding to lysine……. 75mg** **Threonin …… 53mg** **Tryptophan …… 23mg** **Histidin ……... 38mg** **Tyrosin ……..…. 30mg** **Total nitrogen / tablet……..…36mg** **Calcium / tablet…1,25mmol = 50mg**

Decision: Registration Board decided to defer the case for evidence of availability of testing facility for drug product along with analytical procedure.

ii. M/s Biogen Pharma 8-KM Rawat Chak Beli Road Rawat Rawalpindi.

Registration Board in its 295th approved following product of M/s Biogen Pharma 8-KM Rawat Chak Beli Road Rawat Rawalpindi. Firm has submitted request for standardization of label claim as per reference product Ketosteril Tablets approved in Germany. Firm has also submitted fee of Rs.30,000/-. Detail is as under:

Sr. No.	Name of Drug(s) & Composition	Label claim as per RRA (Germany)
1.	Keto Tablet Each film-coated tablet contains: (L-Isoleucine……67mg L-Leucine……. 101mg L-Phenylalanine… 68mg L-Valine ……86mg L-Methionine ……59mg Lysine Acetate ….105mg L-Threonine ……...53mg L-Tryptophan ……23mg L-Histidine ……38mg L-Tyrosine ……..30mg)	**Each film-coated tablet contains:** **α-keto analogue of isoleucine, calcium salt…… 67mg** **α-keto analogue of leucine, calcium salt … 101mg** **α-keto analogue of phenylalanine, calcium salt…68mg** **α-keto analogue of valine, calcium salt…….. 86mg** **α-Hydroxy analogue of methionine, calcium salt…59mg** **Lysine acetate 105mg corresponding to lysine……. 75mg** **Threonin …… 53mg** **Tryptophan …… 23mg** **Histidin ……... 38mg** **Tyrosin ……..…. 30mg** **Total nitrogen / tablet……..…36mg** **Calcium / tablet…1,25mmol = 50mg**

Decision: Registration Board decided to defer the case for evidence of availability of testing facility for drug product along with analytical procedure.

iii. M/s. Amson Vacines & Pharma (Pvt) Ltd. Plot No.154 Industrial Triangle Kahuta Road, Islamabad.

Registration Board in its 317th approved following product of M/s Amson Vacines & Pharma (Pvt) Ltd. Plot No.154 Industrial Triangle Kahuta Road, Islamabad. Firm has submitted request for standardization of label claim as per reference generic / comparator product i.e, Osnate –D Suspension Reg. No. 070854 of M/s. AGP, Karachi. Firm has also submitted fee of Rs.30,000/-. Detail is as under:

Sr. No.	Name of Drug(s) & Composition	Label Claim As Per Generic Product
1.	Osso-D Suspension 60ml / 120ml Each 5ml Contains Ossien Mineral Complex (Microcrystalline Hydroxyapatite	**"Each 5ml contains:** **Ossein Mineral Complex (Microcrystalline Hydroxyapatite complex) …… 400mg** **Equivalent to:** **Calcium……85.59mg**

	complex) …400mg Vitamin D … 400IU	**Phosphorous……39.61mg** **Residual Mineral Salt…12mg** **Collagen……...107.95mg** **Other Protein……32mg** **Vitamin D.....400IU** **Trace Element … (Fi, Mg, Fe, Zn, Cu, Ni.)"**

Decision: Registration Board decided to approve the correction in above product with following details.

"Each 5ml contains:
Ossein Mineral Complex (Microcrystalline Hydroxyapatite complex) …… 400mg
Equivalent to:
Calcium……85.59mg
Phosphorous……39.61mg
Residual Mineral Salt…12mg
Collagen……...107.95mg
Other Protein……32mg
Vitamin D.....400IU
Trace Element … (Fi, Mg, Fe, Zn, Cu, Ni.)"

iv. M/s. Shaigan Pharmaceutical (Pvt) Ltd. 14-Km Adyala Road Post Office Dahgal Rawalpindi

Registration Board in its 295th meeting approved following product of M/s. Shaigan Pharmaceutical (Pvt) Ltd. 14-Km Adyala Road Post Office Dahgal Rawalpindi. Registration letter was not issued as strength was mentioned as 100mg instead of 500mg. Firm has also submitted fee of Rs.30,000/-. Detail is as under:

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition
1.	Azitrax 500mg Injection Each ml Contains: Azithromycin as Dihydrate (Lyophilized) Eq. to Azithromycin…….100mg	Azitrax 500mg Injection Each vial Contains: Azithromycin as Dihydrate (Lyophilized) Eq. to Azithromycin…….500mg

Decision: Registration Board decided to approve the correction in above product with following details.

"Azitrax 500mg Injection
Each vial Contains:
Azithromycin as Dihydrate (Lyophilized)
Eq. to Azithromycin…….500mg"

v. M/s. Pharmasol (Pvt) Ltd Plot 549, Sunder Industrial estate, Lahore.

Registration Board in its 297th meeting approved following product of M/s. Pharmasol (Pvt) Ltd Plot 549, Sunder Industrial estate, Lahore. Registration letter was not issued as correction is required in formulation as per RRA as approved formulation in MHRA contains Hypromellose instead of Methylcellulose. Firm has also submitted fee of Rs.30,000/-. Detail is as under:

Sr. No.	Name of Approved Drug(s) & Composition	Corrected Name of Drug(s) & Composition
2.	Eyesol 0.1% W/V+0.3% Opthalmic Solution Each ml contains: Dextran 70 …….. 1mg Methylcellulose…… 3mg	Eyesol 0.1% W/V+0.3% Opthalmic Solution Each ml contains: Dextran 70 …….. 1mg Hypromellose …… 3mg

Decision: Registration Board decided to approve the correction in above product with following details.

Each ml contains:
Dextran 70 …….. 1mg

Hypromellose …… 3mg

Case No.06: Cancellation Registration of Drugs in lieu of cancellation of DML/Surrender of Sections

Central Licensing Board in its 284th meeting held on 16-12-2021 cancelled Drug manufacturing licenses of following firms. Detail is as under;

Sr. No.	Name of Firm	Decision of CLB
1.	M/s. Hygeia Pharmaceuticals Plot No. 295 Industrial Triangle Kahuta Road Islamabad 000523	**The Central Licensing Board considered the facts and decided to accede the request of M/s Hygeia Pharmaceuticals, Plot No.295, Indushial Triangle, Kahuta Road Islamabad for voluntary surrender of Injectable (Steroidal /Hormone) Section with immediate effect. Therefore, Injectable (Steroidal/Hormone) Section in the name of M/s Hygeia Pharmaceuticals, Islamabad stands cancelled. [1-4/2000-Lic (Vol-III) dated 30-05-2022]**

Registration Board in its 307th meeting has authorized its Chairman for issuance of show cause notice for cancellation of registration after cancellation of DML. Accordingly, M/s. Hygeia Pharmaceuticals Plot No. 295 Industrial Triangle Kahuta Road Islamabad was issued show cause notice.

Now, firm has been called for personal hearing at 02:00 P.M.

Proceedings and Decision of 323rd meeting of Registration Board:

Sr. No.	Name of Firms	Proceedings of 323rd meeting of Registration Board	Decision of 323rd meeting of Registration Board
1.	M/s. Hygeia Pharmaceuticals Plot No. 295 Industrial Triangle Kahuta Road Islamabad 000523	The firm was issued showcause and personal hearing notices to appear before the Registration Board. No one appeared before 322nd meeting of Registration Board. No one appear on behalf of firm	**Keeping in view the decision taken by the Central Licensing Board in its 284th Meeting regarding withdrawal of licensed section, the Registration Board deliberated and cancelled all drug products registered under Injectable (Steroidal/Hormone) Section of M/s. Hygeia Pharmaceuticals Plot No. 295 Industrial Triangle Kahuta Road Islamabad.**

Case No.07: M/s. DeMont Research Laboratories (Pvt) Ltd. 20-Km, Lahore Sharikpur Road, Sheikhupura

Registration Board in its various meetings approved following products of M/s. DeMont Research Laboratories (Pvt) Ltd. 20-Km, Lahore Sharikpur Road, Sheikhupura. Registration letters of these products are not issued due to reseons mentioned against each which have also been communicated to firm vide letter No. F.5-1/2021-Reg-II (M-297) dated 04-08-2022, No. F.5-5/2021-Reg-II (M-312) dated 26-10-2022 and No. F.5-2/2022-Reg-II (M-316) dated 26-10-2022. Despite of two reminders dated 28-09-2022 and 26-10-2022 firm has not yet submitted the reply of shortcoming communicated vide letters as stated above. Detail is as under:

Sr. No.	Product name	Reason(s) for non- issuance of registration letter	Meeting Number
1.	Lispril 5mg Tablet Each tablet contains: Lisinopril as dihydrate…….5mg Manufacturers	i. Submission of fee for change of title of firm.	M-297

2.	Lispril 10mg Tablet Each film- coated tablet contains: Lisinopril as dihydrate……10mg Manufacturers	i. Submission of fee for change of title of firm.	M-297
3.	Carvidem Tablet 6.25mg Each film coated tablet contains: Carvedilol……6.25mg Manufacturers	i. Submission of fee for change of title of firm.	M-297
4.	Carvidem 12.5mg Tablet Each film- coated tablet contains: Carvedilol……12.5mg Manufacturers	i. Submission of fee for change of title of firm.	M-297
5.	Carvidem 25mg Tablet Each film- coated tablet contains: Carvedilol……...25mg Manufacturers	i. Submission of fee for change of title of firm.	M-297
6.	Amsolide 100mg Tablet Each Film Coated Tablet Contains: Nimesulide…100mg Innovators Specification	i. Submission of fee for change of title of firm.	M-297
7.	Hiace 2.5mg Tablet Each uncoated tablet contains: Ramipril……2.5mg Manufacturers	i. Submission of fee for change of title of firm.	M-297
8.	Amlod 5mg Tablet Each tablet contains: Amlodipine Besylate Eq. to Amlodipine……5mg Manufacturers	i. Submission of fee for change of title of firm. ii. Submission of alternate brand names.	M-297
9.	Astra 20mg Tablet Each film- coated tablet contains: Atorvastatin as calcium trihydrate…….20mg	i. Submission of fee for change of title of firm. ii. Submission of alternate brand names.	M-297
10.	Equlip Capsule 200mg Each capsule contains: Fenofibrate……..200mg	i. Submission of fee for change of title of firm. ii. Submission of alternate brand names.	M-297
11.	Amlod Tablet 10mg Each tablet contains: Amlodipine besylate eq. to Amlodipine……..10mg	i. Submission of fee for change of title of firm. ii. Submission of alternate brand names.	M-297
12.	Carsel 100mg Tablet Each film- coated tablet contains: Metoprolol tartrate…...…100mg	i. Submission of fee for change of title of firm. ii. Submission of alternate brand names.	M-297
13.	Cande 8mg Tablet Each uncoated tablet contains: Candesartan Cilexetil …..8mg	i. Submission of fee for change of title of firm.	M-297
14.	Valtan 80mg Tablet Each film- coated tablet contains: Valsartan……80mg	i. Submission of fee for change of title of firm. ii. Submission of alternate brand names.	M-297
15.	Astra 10mg Tablet Each film- coated tablet contains:	i. Submission of fee for change of title of firm.	M-297

	Atorvastatin as calcium trihydrate…….....10mg	ii. Submission of alternate brand names.	
16.	Valtan 160mg Tablet Each film- coated tablet contains: Valsartan……..160mg	i. Submission of fee for change of title of firm. ii. Submission of alternate brand names.	M-297
17.	Anitex tablet 85mg/ 500mg Each film- coated tablet contains: Sumatriptan as Succinate……...85mg Naproxen Sodium ……500mg	i. Submission of fee for change of title of firm.	M-297
18.	Mondex Ophthalmic Solution. Each ml contains: Tobramycin…….3mg Dexamethasone……...1mg USP	i. Confirmation of separate dispensing booth for steroidal materials is required. ii. Submission of fee for change of title of firm.	M-312
19.	Emeb 10mg Tablet (ezetimibe) Each tablet Contains: Ezetimibe…10mg	i. Fee of Rs.30,000/- for correction/pre-approval change in composition (correction/change of applied drug in form 5), as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021 is required.	M-316

Proceeding of the meeting

Registration Board was appraised that firm has now submitted requisite fee for above mentioned products.

Decision: Registration Board advised to issue registration letter as firm has deposited requisite fee. The Board further advised to send a reminder to all such pending cases and in case of non-compliance, authorized Chairman Registration Board for issuance of show cause foe cancellation of registration.

Case No. 08 M/s. Change of Manufacturer Abroad of Approved Product of M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore

Registration Board in its 297th meeting approved the following product of M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore. Detail is as under;

Sr.#	Product Name and Composition	Decision of 297th Meeting of RB.
1.	MAXVAS soft capsule 0.5mg Each soft gelatin capsule contains: Dutasteride……0.5mg Innovator's specification	**Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad. M/s CCL Pharmaceuticals (Pvt) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore will perform primary and secondary packaging and will be responsible for the Quality control testing and batch release of finished drug product.**

Name, address of manufacturer:

M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam

Name and address of marketing authorization holder (abroad):

M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam

While issuing registration letter, it was transpired that manufacturer abroad which was also mentioned on CoPP, have not approved manufacturing facility of Soft Gel Capsule. Hence, registration letter was not issued.

Now, firm has submitted revised Legalized CoPP (Issuance date 29-07-2022) in which manufacture name is M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An

District, Binh Duong, Vietnam. Firm has also submitted fee of Rs.150000/-, verified from website for correction in name of manufacturer abroad and has also corrected address of manufacturer in registration application.

Decision: **Registration Board decided to approve the correction in name of manufacturer of above product with following details.**
"M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam"

Case No.9: Registration Status of Formulations (Diclofenac Potassium 75mg & 100mg, Famotidine 10mg/5ml and combination drug product containing Paracetamol + Thioridazine + Caffeine.

Registration Board in its 317th meeting while considering the case of Diclofenac Potassium 75mg & 100mg, Famotidine 10mg/5ml Suspension and combination drug product containing Paracetamol + Thioridazine + Caffeine on grounds of non-availability of safety and efficacy data as these formulations are neither approved in any of the Reference Regulatory Authorities nor any registration holder / manufacturer submitted data establishing safety and efficacy of these formulations and safety and efficacy profile cannot be established in the absence of a well-established system for reporting of adverse events, decided as under:

For Diclofenac Potassium:

In light of the foregoing discussions, risk-benefit analysis and public health impact of Diclofenac Potassium 75mg and 100mg, the Board made following decisions:

i. Suspended all drug registrations of Diclofenac Potassium 75mg and 100mg under Section 7 (11) (d) read with Section 42 of the Drugs Act, 1976 in the larger public interest, with immediate effect as these are neither approved by any Reference Regulatory Authority nor any safety and efficacy data regarding them is available with any registration holder. Period of suspension will be for one (01) year or till demonstration of its safety and efficacy by conducting indigenous clinical trials in accordance with the Bio Study Rules, 2017 or its approval by the Reference Regulatory Authorities, whichever is earlier. After provision of aforementioned data, cases of such pharmaceutical firms shall be considered on merit by Registration Board.
ii. Suspended manufacturing and import of these drug products immediately and directed to withdraw available stocks from the market in the larger public interest. QA&LT Division, DRAP will monitor and implement the decision in coordination with the respective provincial governments.
iii. Recommended Licensing Division, DRAP for approval of Qualified person for Pharmacovigilance (QPPV) / Local Safety Officer (LSO) whichever is applicable in licensed pharmaceutical units and advised PE&R and BE&R Divisions for implementing similar action for importers of finished drug products as required under Pharmacovigilance Rules, 2022.
iv. Final decision regarding pharmaceutical firms who have obtained interim relief from the Hon'ble Lahore High Court, Lahore shall be announced after decision and direction by the Hon'ble Court. Legal Affairs Division is requested to place the instant decision before the Hon'ble Court and seek expeditious disposal of the matter in the larger public interest.
v. Recommended DRAP Authority for out of queue consideration of registration applications of Diclofenac Potassium 50mg, 25mg and 12.5mg Tablet and 50mg Sachet in order to facilitate the registration holders affected by the instant decision.

For Famotidine Suspension:

In light of the foregoing discussions, risk-benefit analysis and public health impact of Famotidine 10mg/5ml and 40mg/5ml, the Board made following decisions:

i. Suspended all drug registrations of Famotidine 10mg/5ml and 40mg/5ml Liquid Suspension under Section 7(11)(d) read with Section 42 of the Drugs Act, 1976 in the

larger public interest, with immediate effect as neither approved by any Reference Regulatory Authorities nor efficacy data is available with any registration holder. Period of suspension will be for one (01) year or till demonstration of efficacy by conducting indigenous clinical trials in accordance with Bio Study Rules, 2017 or approval by Reference Regulatory Authorities whichever is earlier. After provision of aforementioned data, cases of such pharmaceutical firms shall be considered on merit by the Registration Board

ii. Suspended manufacturing and import of these drug products immediately and directed to withdraw available stocks from the market in the larger public interest. QA&LT Division, DRAP will monitor and implement the decision in coordination with the respective provincial governments.

iii. Final decision regarding pharmaceutical concerns who have obtained interim relief from the Hon'ble Lahore High Court, Lahore shall be announced after decision and direction by the Hon'ble Court. Legal Affairs Division is requested to place the instant decision before the Hon'ble Court and seek expeditious disposal of the matter in the larger public interest.

iv. Recommended DRAP Authority for out of queue consideration of registration applications of Famotidine 40mg/5ml Dry Suspension in order to facilitate the registration holders affected by the instant decision.

For Formulation containing Paracetamol 500mg, Thioridazine 3mg and Caffeine 70mg

In light of the foregoing discussions, risk-benefit analysis and public health impact of the combination (Paracetamol 500mg, Thioridazine 3mg and Caffeine 70mg), the Board made following decisions:

i. Suspended all drug registrations of the combination (Paracetamol 500mg, Thioridazine 3mg and Caffeine 70mg) under Section 7 (11) (b, c & d) read with Section 42 of the Drugs Act, 1976 in the larger public interest, with immediate effect as neither approved by any Reference Regulatory Authorities nor safety and efficacy data is available with any registration holder. Period of suspension will be for 1 year or till sharing of safety and efficacy data either by conducting clinical trials (to establish safety and efficacy) in accordance with the Bio-Study Rules, 2017 or approval by Reference Regulatory Authorities whichever is earlier. After provision of aforementioned data, cases of such pharmaceutical firms shall be considered on merit by the Registration Board.

ii. Suspended manufacturing and import of these drug products immediately and directed to withdraw available stocks from the market. QA&LT Division, DRAP will monitor and implement the decision in coordination with the respective provincial governments.

iii. Recommended Licensing Division, DRAP for approval of Qualified person for Pharmacovigilance (QPPV) / Local Safety Officer (LSO) whichever is applicable in licensed pharmaceutical units and advised PE&R and BE&R Divisions for similar action for importers of finished drug products as required under Pharmacovigilance Rules, 2022.

Accordingly, suspension letters have been issued to all the firms. However, inadvertently following registration holders of Famotidine Suspension 10mg/5ml and Diclofenac Potassium 75mg & 100mg Tablet could not be included in the list previously presented before the Board. Detail is as under;

Famotidine Suspension 10mg/5ml			
Sr. No.	**Reg. No.**	**Brand Name & composition**	**Registration Holder**
1.	025157	Gimed Suspension Each 5ml contains:- Famotidine 10mg	M/s. Albro Pharmaceutical (Pvt) Ltd. 340-S Industrial Area, Lahore.
2.	027948	Famron Suspension	M/s. PDH Pharmaceuticals Pvt Ltd, 19-km, Ferozpur Road, Lahore

		Each 5ml contains:- Famotidine 10mg	
3.	059498	Fedcid Suspension Each 5ml contains:- Famotidine USP……..10mg	Fedro Pharmaceutical Labs (Pvt) Ltd. 149-Industrial Estate Jamrud Road Peshawar.
Diclofenac Potassium 75mg Tablet			
1.	022485	Ostefen 75mg Tablet Each tablet contains:- Diclofenac Potassium….75mg	Saydon Pharmaceutical Industries (Pvt) Ltd. 77/A Hayatabad Industrial Estate Peshawar
2.	036815	Dic-P 75mg Tablets Each tablet contains:- Diclofenac Potassium….75mg	M/s. Shaheen Pharmaceuticals 3 K.M Murghzar Road Saidu Sharif Swat
3.	058262	Velflex 75mg Tablet Each film coated tablet contains:- Diclofenac Potassium...75mg	Kaizen Pharmaceuticals (Pvt) Ltd. Plot No. E-127 E-128 & E-129 North Western Industrial Zone Port Qasim Authority Karachi
4.	058263	Velflex 100mg Tablet Each film coated tablet contains:- Diclofenac Potassium...100mg	Kaizen Pharmaceuticals (Pvt) Ltd. Plot No. E-127 E-128 & E-129 North Western Industrial Zone Port Qasim Authority Karachi

Case was presented before Registration Board in its 320th meeting and the Board decided as under

"Registration Board deferred the case for decision of Drugs Appellate Board."

Various firms had submitted appeals before the Appellate Board against the decision of 317th meeting of the Registration Board regarding suspension of Diclofenac Potassium 75 &100mg, Famotidine 10mg/5ml suspension and Paracetamol + Thioridazine + Caffeine (Diagesic-P) containing Drug products. Details of firms is as under:

Sr. No.	Appeal No.	Appellant
1.	02/2022	M/s. Quaper (Pvt) Ltd. 26-A S.I.E. Lahore Road Sargodha
2.	13/2022	M/s Caraway Pharmaceuticals, Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat.
3.	17/2022	M/s Batala Pharmaceuticals, 23/B Small Industrial Estate No. 2 Near Wapda Town, Khiali Bypass Gujranwala
4.	18/2022	M/s Hilton Pharma (Pvt) Ltd., Plot No. 13 & 14 Sector 15 Korangi Industrial Area Karachi.
5.	19/2022	M/s Sunshine Pharmaceuticals, Emanabad, G.T. Road, Gujranwala
6.	20/2022	M/s Barrett Hodgson Pakistan (Pvt) Ltd., F/423 SITE Karachi.
7.	21/2022	M/s Kaizen Pharmaceuticals (Pvt) Ltd., Plot No. E-127 E-128 & E-129 North Westren Zone Port Qasim Authority Karachi.
8.	22/2022	M/s Pearl Pharmaceuticals, Plot No 204 Street No. 1 I-10/3 Industrial Area Islamabad.
9.	23/2022	M/s Platinum Pharmaceuticals (Pvt) Ltd., A/20 North Western Industries Zone Bin Qasim Karachi.
10.	24/2022	M/s Medera Pharmaceuticals (Pvt) Ltd., 249-A Industrial Triangle Kahuta Road Islamabad.
11.	25/2022	M/s Cibex (Pvt) Ltd., F-405 S.I.T.E Karachi.
12.	26/2022	M/s Tabros Pharma (Pvt) Ltd., Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area Karachi.

13.	27/2022	M/s Rogen Pharmaceuticals, Plot No. 30 S-4 National Industrial Zone Rawat Islamabad.
14.	12/2022	M/s Wilson's Pharmaceuticals, 387-388 Sector I-9 Industrial Area Islamabad.
15.	14/2022	M/s Scotmann Pharmaceuticals, Plot No. 5-D, Sector I-10/3 Islamabad.
16.	16/2022	M/s Medisearch Pharmacal (Pvt) Ltd., 5 Km Raiwind Manga Road, Lahore.

Accordingly, Appellate Board in its 162nd meeting held on 30th August, 2022 decided as under:

A. <u>For Diclofenac Potassium 75mg & 100mg</u>

i. **Allow the appeals and resumption of the manufacturing and sale of the drugs Diclofenac Potassium 75mg & 100mg.**
ii. **The pack size of 100 mg tablet will be reduced to pack of three tablets in order to avoid misuse potential.**
iii. **Sale of both drugs will be prescription only by a qualified practitioner.**
iv. **Pharmacovigilance data will be generated and submitted regularly to the Pharmacy Services Division in accordance with Pharmacovigilance Rules, 2022.**
v. **The manufacturer will provide safety and efficacy studies approved by any credible sources to Pharmacy Services Division for review and submission to Registration Board. If no such studies are available, the PPMA will contact Pharmacy Services Division for conduction of safety and efficacy trial as per Bio Study Rules, 2017.**
vi. **This decision will be applicable to only those firms/companies who are in appeals before the Appellate Board.**
vii. **After the safety and efficacy data establishment, the Registration Board will consider the pending and new applications of this drug.**

B. <u>For Famotidine</u>

i. **Allow the appeals and resumption of the manufacturing and sale of the product Famotidine.**
ii. **Sale of this drug will be prescription only by a qualified practitioner.**
iii. **The manufacturer will provide efficacy studies approved by any credible sources to Pharmacy Services Division for review and submission to Registration Board. If no such studies are available, the PPMA will contact Pharmacy Services Division for conduction of safety and efficacy trial as per Bio Study Rules, 2017.**
iv. **This decision will be applicable to only those firms/companies who are in appeals before the Appellate Board.**
v. **After establishment of the efficacy data, the Registration Board will consider the pending and new applications of this drug.**

C. <u>For Diagesic-P (Formulation containing Paracetamol 500mg, Thioridazine 3mg and Caffeine 70mg)</u>

i. **Allow the appeals and resumption of the manufacturing and sale of the product Diagesic-P Tablet.**
ii. **Sale of this drug will be prescription only by a qualified practitioner.**
iii. **Pharmacovigilance data will be generated and submitted regularly to the Pharmacy Services Division in accordance with Pharmacovigilance Rules, 2022.**
iv. **The manufacturer will provide efficacy studies approved by any credible sources to Pharmacy Services Division for review and submission to Registration Board. If no such studies are available, the firm will contact Pharmacy Services Division for conduction of safety and efficacy trial as per Bio Study Rules, 2017.**
v. **After establishment of the efficacy data, the Registration Board will consider the pending and new applications of this drug.**

Following firms have filed petitions in Lahore High Court and obtained interim relief. Detail of firms along with their products is as under:

Sr. No.	Registration Holder	Reg. No.	Brand Name & composition
1.	Paramount Pharmaceuticals, 36 Industrial Triangle, Kahuta Road Islamabad.	052727	Ronset SR Tablets Diclofenac Potassium ...100mg
		033996	Pepton Suspension Each 5ml Contains:- Famotidine…..10mg
2.	Siza International (Pvt) Ltd, 18 KM, Main Ferozepur Road, Lahore	024049	Rheumatin-K Tablet 75mg Diclofenac Potassium ... 75mg
		025568	Ulcenil Suspneion Each 5ml Contains:- Famotidine....10mg
3.	Davis Pharmaceutical Laboratories, Plot No. 121 Industrial Triangle Kahuta Road Islamabad.	041945	Mobil K 75mg Tablet Diclofenac Potassium ... 75mg
		063176	Mobil-K 100mg Tablets Diclofenac Potassium ...100mg
4.	Quaper (Pvt) Ltd., 26-A S.I.E. Lahore Road Sargodha.	046202	Kaymax Tablet Diclofenac Potassium ... 75mg
5.	Shrooq Pharmaceuticals (Pvt) Ltd, 21-Km Ferozepur Road, Lahore.	064791	Pointer 75 Capsule Diclofenac Potassium ... 75mg
		040304	Moven 75mg Tablet Diclofenac Potassium ... 75mg
		040312	Fomen Suspension 10mg Each 5ml Contains:- Famotidine…..10mg
6.	Pakheim International Pharma (Pvt) Ltd., 28 Km Ferozepur Road Lahore., Lahore	023973	Fen-K SR Tablet 100mg Diclofenac Potassium ... 10mg
7.	Sapient Pharma, 123-S Industrial Area Kot Lakhpat Lahore.	069281	Zainex 75mg Tablets Diclofenac Potassium ... 75mg
8.	M/s Pakistan Pharmaceutical Products (Pvt) Ltd., D-122, Sindh Industrial Trading Estate, Karachi.	055103	Famdin Suspension Each 5ml Contains:- Famotidine……10mg

For those who have obtained interim relief from Lahore High Court, Registration Board decided as under:

> **"Final decision regarding pharmaceutical firms who have obtained interim relief from the Hon'ble Lahore High Court, Lahore shall be announced after decision and direction by the Hon'ble Court. Legal Affairs Division is requested to place the instant decision before the Hon'ble Court and seek expeditious disposal of the matter in the larger public interest."**

All the firms have withdrawn their writ petition filed in Lahore High Court, Lahore and court vide orders dated 27-09-2022 decided for all petition as "Dismissed as withdrawn".

Decision: Registration Board after thorough deliberation decided as under:

i. **Deferred above cases of Diclofenac Potassium 75 and 100mg Tablet / Capsule and Famotidine 10mg/5ml Liquid Suspension for the opinion of Legal Affair's Division for their fate in light of Appellate Board and LHC orders.**
ii. **In order to dispose of new applications of Diclofenac Potassium 75 & 100mg Tablet / Capsule and Famotidine 10mg/5ml Liquid Suspension, the Board requested Pharmacy Services Division to intimate PE&R Division regrading provision of safety and efficacy**

studies approved by any credible sources and shared by manufacturers and if no such studies are available then PPMA will conduct safety and efficacy trial as per Bio study Rules, 2017, as decided by Appellate Board in 162nd meeting.

Case No. 10: Allocation of Quota for Control Substances Ephedrine HCl for the year 2017 to M/s. Sharex Laboratories, Sadiqabad.

The case of M/s. Sharex Laboratories, Sadiqabad was considered in 275th and 286th meeting of Registration Board as per detailed below:-

2. Proceedings of 275th Meeting of Registration Board:

The instant case was presented based on the letter received from Assistant Director (CD) (Dated 21st Sep, 2017) wherein it has been stated that M/s Sharex Laboratories, sadiqabad applied for quota allocation of product Tracodil syrup (Reg. 003158). The case was presented before 43rd meeting of committee on allocation of controlled drug held on 26th July, 2017, the committee deferred the case for issuance of show cause by DRAP for manufacturing of Tracodil syrup (Reg. 003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of Tracodil syrup (Reg. 003158) 400ml pack size.

The approved pack sizes of product Tracodil Syrup‖ (Reg. No. 003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October 1988).

3. Decision of 275th meeting of Registration Board:

Registration decided to call M/s Sharex Laboratories, Sadiqabad for personal hearing and for deliberating above mentioned matter before the Registration Board.

4. **Proceedings of 286th meeting of Registration Board:**

Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm for applying quota of 400ml pack size of product Tracodil syrup (Reg.003158) without approval.

5. Decision of 286th meeting of Registration Board:

Registration Board in its 286th meeting decided to refer the case to Legal Affair division for legal opinion.

6. Accordingly, the case was refer to Legal Affairs, Division and in response, Legal Affairs, Division has provided following opinion:

i. That M/s. Sharex Laboratory applied for the quota allocation of product Tracodil Syrup (Reg.No.003158).

ii. That the Committee on Allocation of Controlled Drugs held on 26.07.2017 deferred the case for issuance of show cause by DRAP for manufacturing of "Tracodil Syrup" (Reg.No.003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of "Tracodil Syrup" (Reg.No.003158) and 60ml (dated 27th October, 1988).

iii. That the approved pack size of the product "Tracodil Syrup" (Reg.No.003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October, 1988).

iv. That Mr. Muhammad Ishfaq production pharmacist, appeared in 286th meeting before Board and apologized on behalf of the firm for applying quota of 400ml pack size of product "Tracodil Syrup" (Reg.No.003158) without approval.

v. That the Registration Board in 286th meeting referred the case to Legal Affairs, Division for legal opinion.

vi. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(a)(f) prohibit to supply an incorrect, incomplete or misleading information when required to furnish any information under this Act or the rules.

vii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

7. Decision of 289th meeting of Registration Board:

In light of the opinion of Legal Affair's Division on the matter, Registration Board deliberated the case and decided to issue show cause notice to M/s Sharex Laboratories, Sadiqabad for violation of condition of drug registration, as follows:

- Cancellation of registration.
- Suspension of registration.
- Prosecution in Drug Court

8. Accordingly, show cause notice was served to M/s. Sharex Laboratories, Sadiqabad.

9. Registration Board in its 295th meeting deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

10. In 296th meeting M/s. Sharex Laboratories, Sadiqabad was called for personal hearing. Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm and stated that firm was unaware about the approval of pack sizes of Tracodil Syrup (Reg.No.003158) as on initial registration letter no pack size was written. He has further stated that firm will submit all the relevant documents / approvals granted by DRAP regarding said product.

11. Registration Board in 296th meeting deferred the case for further deliberation after submission of documents as stated by representative of the firm.

In compliance with 296th meeting of Registration Board firm has submitted following documents;

i. Initial registration letter of Ammonium Chloride Syrup Reg. No. 003158 dated 06-11-1977 in which Pack size & MRP are not mentioned.

ii. Change of brand name letter from Ammonium Chloride Syrup to Tracodil Cough Syrup dated 16-08-1979

iii. Price revision of locally manufactured / fixation of prices of additional packs letter dated 27-10-1988 in which Pack sizes along with MRPs are mentioned with following details;

Sr. No.	Reg. No.	Name of Drug	Packing	MRP
1.	003158	Tracodil Cough Syrup	120ml 60ml 450ml	8.00 5.00 18.50

12. **Decision of 308th Meeting of registration Board:**

Registration Board after through deliberation decided as follows:

- Referred the case to Costing & Pricing Division for proceeding as per rules for overcharging of MRP.
- Manufacturing of product as per approval granted by relevant forums.

13. Accordingly, above decision of Registration Board was communicated to Costing & Pricing Division and reply of said Division is as under;

"In light of opinion of the Legal Division, the matter is of selling of an un-approved pack size which may fall under violation of the conditions of Registration. Moreover, no evidence of overpricing has been provided. Therefore, Division of PE&R may proceed in accordance with the opinion of the Legal Division."

14. Opinion of Legal Affair's Division is as under;

i. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(f) prohibit to supply an incorrect, incomplete or misleading information when required to furnish any information under this Act or the rules.

ii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

Decision of 317th meeting of RB

Registration Board deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

As per above decision of the Board, case was referred to **Legal Affairs Division and opinion of said division** is as under:

"The apex courts have guided that Principles of natural justice must be read into each and every statute unless and until it is prohibited by the statute itself---Even if there is no provision as to issuance of notice of personal hearing to the affected party, in a statute, it cannot override the principles of natural justice and an opportunity of a hearing has to be provided to the affected party. Registration Board is statutory Board constituted under Section 7 of the drugs act, 1976. And if some new facts came before the Registration Board regarding the firm, then an opportunity of personal herring may be provided to the firm before final decision of the Board if it thinks fit to fulfill the principle of natural justice. It is pertinent to note that in case of any grievance the firm has alternate remedy of appeal under Section 9 of the drugs act, 1976 before the Appellate Board of the Authority."

Proceedings of 323rd Meeting:

It was discussed in meeting that before proceeding for penalty for prohibitions, as per opinion of the Legal Affair's Division mention in para 14 above, show-cause notice has to be issued to the firm for violation of condition of registration as firm is manufacturing un-approved pack size of their registered product.

Decision: Registration Board decided to issue show-cause notice under Section 7 (11) (c) to M/s. Sharex Laboratories (Pvt) Ltd. KLP Road Sharex Colony, P.O Box No. 11, Sadiqabad District Rahim Yar Khan for violation of condition of registration.

Case No.03: Issuance of Duplicate Registration Letter

M/s. P.D.H Laboratories (Pvt) Ltd. 9.5-Km Sheikhupura Road (Khaki) Lahore has submitted an application for Duplicate Registration Letter of following products as original registration letters were misplaced during shifting of their head office. Detail of products is as under:

Sr. No.	Registration Number	Brand Name and Composition
1.	**000794**	Aqua Pro Injection 5ml
2.	**000793**	Atropine Injection 1mg/ml
3.	**000784**	Benzyl Pencillin 5 Lac
4.	**000786**	Benzyl Pencillin 10 Lac
5.	**000792**	Chloroquine Phosphate Injection 5ml
6.	**000790**	La'Pen Injection 12 Lac
7.	**000791**	La'Pen Injection 6 Lac
8.	**000785**	Polybiotic Injection 1gm
9.	**000782**	Procaine Penicillin Forte 4 Lac
10.	**000783**	Streptomycin Injection 1gm

Firm has also submitted following documents:

i. Fee of Rs.7500/- each for issuance of duplicate registration letter, verified from website.
ii. Notarized copy of FIR.
iii. Copy of Newspaper in which advertisement reading loss of registration letters was published.
iv. Affidavit regarding contents of application for duplicate registration letter

As per computerized record (RDI) which is also confirmed from The Gazetter of Pakistan, Extra, October, 14, 1981 (Extract enclosed as Anex-I and Anex-II) above mentioned products are registered with following details.

Sr. No.	Registration Number	Brand Name and Composition	Pack Size	MRP

1.	**000794**	Aqua Pro Injection Each ampoule contains: Aqua Pro Injection	100 x 5ml	Rs.30/-
2.	**000793**	Atropine Sulphate Injection Each ml contains: Atropine Sulphate 1mg	1ml x 100	Rs.25/-
3.	**000784**	Benzyl Pencillin Injection 5lac Each vial contains: Benzyl Penicillin 5 lac	1 vial	Rs.1.42/-
4.	**000786**	Benzyl Pencillin Injection 10lac Each vial contains: Benzyl Penicillin 10 lac	1ml	Rs.2.20/-
5.	**000792**	Chloroquine Phosphate Injection Each ml contains: Chloroquine Phosphate 40mg	5ml x 100	Rs.82/-
6.	**000790**	Benzathine Penicillin Injection 12 lac Each vial contains: Benzathine Penicillin 12 lac	1 vial	Rs.4.50/-
7.	**000791**	Benzathine Penicillin Injection 6 lac Each vial contains: Benzathine Penicillin 6 lac	1 vial	Rs.2.45/-
8.	**000785**	Streptomycin Procaine Penicillin Forte Injection Each vial contains: Streptomycin Sulphate 1gm Procaine Penicillin 3,00,000 Units Benzyl Penicillin 1,00,000 Units	1 vial	Rs.2.67/-
9.	**000782**	Procaine Penicillin Forte Injection 4lac Each vial contains: Procaine Penicillin 4 lac	4 lac 20 lac	Rs.1.42/- Rs.4.08/-
10.	**000783**	Streptomycin Injection Each vial contains: Streptomycin Sulphate 1gm	1 vial	Rs.1.50/-

Case was referred to RRR Section for confirmation of renewal status of these products and reply of RRR Section is reproduced as under:

"The renewal applications for the year 2021 and 2016 were submitted within time w.r.t date of registrations as provided by the firm in renewal application.

The section is requested to verify the date of registration from their record as the copies of the registration letters are not submitted by the firm in aforesaid renewal applications."

Decision: Registration Board advised to seek guidance from Legal Affair Division.

Case No.11: Registration of M/s. NBS Pharma 18 Km Raiwind Road Lahore.

Following product of M/s N.B.S Pharma, Lahore were considering 215th meeting of registration board and decided as follows.

Sr. No	Name of Drug	Decision
1.	Povidone-1 Solution Each 100ml contains:- Povidone Iodine USP 7.5gm equivalent to 0.75% available iodine (USP)	Approved subject to the submission of the last Inspection report.

It is submitted that the above cases were discussed in 215th meeting of registration board and decision of the board has been reflected in the above table. The firm has now submitted the

differential free of Rs. 12000/- and submitted the inspection report dated 12.11.2014. which shows details of the section as under: -

External Preparation Section: -

This section comprised of preparation and filling rooms, equipped with preparation vessels of different sizes. Silver san mixer and filling machines was installed HVAC system was provided in this area and was functional at the time of inspection. Re-packing area was equipped with filling machine and different size vessels. HVAC system was installed production area furnish with epoxy.

Registration Board in its 260th meeting deferred the case for GMP status of the firm and confirmation of section either from Licensing division or from panel / renewal inspection report.

The firm has submitted copy of inspection report 20-09-2019 with conclusion that the firm has rectified most of the shortcomings pointed out during last inspection. The panel recommends that M/s. N.B.S Pharma, Lahore may be allowed to resume the production in all sections.

Mr. Ajmal Sohail Asif Area FID vide letter No. 15075/2016-DRAP (L-II) dated 17-10-2016 clarified that the firm has approved external preparation section and is already manufacturing Povidone I Solution, (Povidone Iodine SP. 10gm eq. to 1% Iodine) under Reg. No. 025552

Decision of 296th meeting:

Registration Board deferred the case for confirmation of section approval from Licensing division.

In response to above decision of Registration Board, Licensing Division has forwarded a letter of Regularization of Layout Plan of M/s. NBS Pharma 18 Km Raiwind Road Lahore, dated 07-02-2022 in which following sections are mentioned:

1. External Preparation Section.
2. Liquid Repacking Section.

Decision: Registration Board deferred the case till the approval of regularization of manufacturing facility by the Licensing division.

Case. No.12: Standardization/Correction of Label Claim as Per Reference / Innovator Product.

i. M/s. Elite Pharma (Pvt) Ltd. 9.5 Km Sheikhupura Road Lahore

Registration Board in its 249th meeting approved following product of M/s. Elite Pharma (Pvt) Ltd. 9.5 Km Sheikhupura Road Lahore. Registration letter was not issued due to clarification of fill volume as in brand name it is mentioned as 50ml while in demanded pack size it is 100ml. Firm has requested to correct fill volume as 5ml. Firm has also submitted fee of Rs.30,000/-. Detail is as under:

Sr. No.	Name of Approved Drug(s) & Composition	Pack size approved in 249th meeting	Correct Pack Size
1.	Flucolite Infusion 50ml Each ml contains:- Fluconazole……2mg Manufacturer	Pack of 100ml of 1's	50ml

Decision: Registration Board decided to approve the correction in pack size of above product from 100ml to 50ml.

Case No. 13 Concerns of Health Task Force, M/O. National Health Services Regulations & Coordination, Islamabad

Deputy Director (Costing & Pricing) has forwarded a letter wherein, it was stated that the Drug Pricing Committee (DPC) recommended increase in maximum retail prices of 110 drugs and same were referred to Task Force on Health for review / examination by Federal Cabinet. The Task Force cleared recommendations regarding increase in MRPs of 94 drugs which have been notified vide SRO.1096 (I)/2020 dated 21st October,2020. In case of 16 drugs, the Task Force has not recommended increase in their MRPs since the therapeutic value of these drug is doubtful. List of the 16 drugs were forwarded along with the letter. Detail of products is as under:

S No.	Product Name/Formulation
1.	Multivitamin Syrup (ICI Pakistan)

2.	Neurobion Injection (M/s Martin Dow Marker Ltd)
3.	Theragran-M tablets (M/s GSK Pakistan LTD)
4.	Theragran-H tablets (M/s GSK Pakistan LTD)
5.	Dextromethorphan Hydrobromide + Diphenhydramine hydrochloride + Pseudoephedrine hydrochloride cough Syrup (M/s. Zafa Pharma)
6.	Reltus DM liquid (M/s Pharmatec Pakistan)
7.	Reltus C&F Syrup (M/s Pharmatec Pakistan)
8.	Reltus C&F Tablet (M/s Pharmatec Pakistan)
9.	Cofcol tablet (M/s. Abbott)
10.	Adicos-M Syrup (M/s. Zafa)
11.	Adicos-M Syrup (Zafa)
12.	Trimebutine Maleate tablet 200mg
13.	Trihexyphenidyl HCL tablet 2mg
14.	Paracetamol + Caffeine Tablet
15.	Buscopan Plus tablets (M/s Martin Dow Marker LTD)
16.	Cartigen/Jovit tablets (M/s Getz Pharma)

Furthermore, during fixation of MRP, Health Task Force, M/o. National Health Services Regulations & Coordination, Islamabad also directed to review following formulations with respect to safety reasons of public health issues. Accordingly, registration letters were not issued for these products. Detail of formulations is as under:

1. Esomeprazole + Naproxen Tablets
2. Cimetidine 800mg Tablet

As per directions of Health Task Force, PE&R Division has reviewed all the referred formulations and review report was presented in 297th meeting of the Board. The Board discussed at length and concluded that there are following type of formulations under concern of Task Force: a. Regarding following Multivitamins and cough & cold formulations, Registration Board decided to constitute working group(s) of relevant experts for evaluation of therapeutic value with respect to the quality, safety and efficacy of both cough and cold preparation and Vitamin-Mineral Formulation

- Formulations containing Vitamins-Minerals
- Formulations used in treatment of cough and cold
- Other formulations

Accordingly, Decision of 297th meeting of the Board is reproduced as under:

a. Regarding following Vitamins-Minerals and cough & cold formulations, **Registration Board decided to constitute working group(s) of relevant experts for evaluation of therapeutic value with respect to the quality, safety and efficacy of both cough and cold preparation and Vitamin-Mineral Formulation.**

Detail of formulations along with their status is as under:

i. Formulations containing Vitamins-Minerals

Sr. No.	Product Name/Formulation	Status of Product
1.	Multivitamin Syrup Each 4ml contains: Vitamin B1…….2mg VitaminB2…….2mg Niacinamide…….10mg Vitamin B6…….2mg Calcium Pantothenic acid…2mg Choline……20mg Inositol…….10mg Vitamin B12……5mcg ICI Pakistan	All the ingredients are between RDA to UL limits. Choline and Inositol UL level has not been mentioned in the approved table.
2.	Neurobion Injection	Approved in DMDI Germany

	Each 3ml contains: Vitamin B1(Thiamine Mononitrate)……..100mg Vitamin B6 (pyridoxine Hydrochloride) ….100mg Vitamin B12(cyanocobalamin)…1000mcg (M/s Martin Dow Marker Ltd)	
3.	Theragran-M tablets Each tablet contains: Vitamin A…….5500IU Vitamin D……400IU Vitamin B1……3mg VitaminB2…….3.4mg Vitamin B6…….3mg Vitamin B12….9mcg Niacinamide….30mg Vitamin E….30IU Vitamin C….120mg Calcium Pantothenate….10mg Folic Acid….0.4mg Biotin…….15mcg Calcium ……40mg Iron …….27mg Iodine ……150mcg Magnesium …….100mg Copper….2mg Zinc…….15mg Manganese……5mcg Chromium….5mg Selenium …….10mcg Potassium ….7.5mg Chloride….7.5mg (M/s GSK Pakistan LTD)	All the ingredients are between RDA to UL limits.
4.	Theragran-H tablets Each tablet contains: Vitamin A ….8333IU Vitamin D….133IU Thiamine mononitrate….3.3mg Riboflavin…….3.3mg Pyridoxine HCl…….3.3mg Niacinamide…….33.mg Calcium pantothenate….11.7mg Vitamin E……5IU Vitamin B12…….50mcg Folic Acid…….0.33mg Vitamin C……100mg Copper…….0.67mg Magnesium……41.7mg Iron Elemental (as ferrous Fumarate)...66.7mg (M/s GSK Pakistan LTD)	All the ingredients are between RDA to UL limits except elemental Iron as the UL limit of elemental iron is 60mg while the amount used in the formulation is 66.7mg.

ii. Formulations used in treatment of cough and cold

Sr. No.	Product Name/Formulation	Status of Product
1.	Dextromethorphan Hydrobromide + Diphenhydramine hydrochloride + Pseudoephedrine hydrochloride cough Syrup Each 5ml contains: Dextromethorphan hydrobromide….6.5mg Diphenhydramine Hydrochloride….14mg Pseudoephedrine hydrochloride ….22.5mg Zafa Pharma	Approval status in RRA has not been confirmed.
2.	Dextromethorphan Hydrobromide + Diphenhydramine hydrochloride + Pseudoephedrine hydrochloride cough Syrup Each 5ml contains: Dextromethorphan hydrobromide….6.5mg Diphenhydramine Hydrochloride….14mg Pseudoephedrine hydrochloride ….22.5mg Zafa Pharma	Approval status in RRA has not been confirmed.
3.	Reltus DM liquid Each 5ml syrup contains: - Dextromethorphan HBr….10mg Pseudoephedrine HCL….30mg Chlorpheniramine Maleate (M/S PHARMATEC PAKISTAN)	Approval status in RRA has not been confirmed.
4.	Reltus C&F Syrup Each 5ml syrup contains: Paracetamol…….80mg Pseudoephedrine HCl….15mg Chlorpheniramine Maleate…….1mg (M/S PHARMATEC PAKISTAN)	Approval status in RRA has not been confirmed.
5.	Reltus C&F Tablet Each tablet contains: - Paracetamol….600mg Pseudoephedrine HCl….60mg Chlorpheniramine Maleate…4mg (M/S PHARMATEC PAKISTAN)	Approval status in RRA has not been confirmed.
6.	Cofcol tablet Each tablet contains: Paracetamol ….325mg Pseudoephedrine HCl….30mg Dextromethorphan HBr….10mg Chlorpheniramine Maleate….1mg Vitamin C….50mg (Abbott)	Approval status in RRA has not been confirmed.
7.	Adicos-M Syrup Each 5ml contains: - Dextromethorphan Hydrobromide B.P….6.5mg Diphenhydramine Hydrochloride B.P….14mg Pseudoephedrine Hydrochloride B.P….22.5mg	Approval status in RRA has not been confirmed.

	Menthol B.P….1.75mg (Zafa)	

iii. Other formulation

Sr. No.	Product Name/Formulation	Status of Product
1.	Cartigen/Jovit tablets Each tablet contains: Glucosamine Sulphate …500mg Chondroitin sulphate….400mg M/s Getz Pharma	Approval status in RRA has not been confirmed.

b. Regarding following other formulations, **Registration Board endorsed its decision regarding grant of registration and advised to inform Task Force on Health about above mentioned status. For Naproxen + Esomeprazole and Cimetidine, registration letters will be issued after response of Health Task Force."**

Sr. No.	Product Name/Formulation	Status of Product
1.	Trimebutine Maleate tablet 200mg Each tablet contains: Trimebutine Maleate…….200mg	Approved in Health Canada
2.	Trihexyphenidyl HCL tablet 2mg Each tablet contains: Trihexyphenidyl HCL…….2mg	Approved in FDA
3.	Paracetamol + Caffeine Tablet Each tablet contains: - Paracetamol BP….500mg Caffeine …….65mg	Approved in MHRA, as film coated tablet
4.	Buscopan Plus tablets Each film-coated tablet contains: Hyoscine-N Butyl bromide….10mg Paracetamol……500mg (M/s Martin Dow Marker LTD)	Approved in DMDI Germany
5.	Esonap 20/500 Tablet (Naproxen 500mg+Esomeprazole as Magnesium 20mg) of M/ s Dyson Research Laboratories (Pvt.) Ltd. 28th KM Ferozpur Road, Lahore.	Approved in USFDA, EMA and MHRA
6.	Promig plus tablets 500mg/20mg (Naproxen 500mg + Esomeprazole as magnesium 20mg) of M/s Global Pharmaceuticals (Pvt.) Ltd, Plot No. 204-205,, Industrial Triangle, Kahuta Road, Islamabad.	
7.	Esonap 20/500 Tablet (Naproxen 500 mg + Esomeprazole as Magnesium 20mg) of M/s. Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22 - 23, Industrial Estate, Kahuta road, Model Town, Islamabad.	
8.	Promig plus tablets 375mg/20mg (Naproxen 375mg + Esomeprazole as magnesium 20mg) of M/s Global Pharmaceuticals (Pvt.) Ltd, Plot No.	

	204-205,, Industrial Triangle, Kahuta Road, Islamabad.	
9.	Cimtid Fort tablet 800mg (Cimetidine 800mg) of M/s Semos Pharmaceuticals, Pvt. Limited, Plot # -Sector 12 ,11A, North Karachi Industrial Area, Karachi.	Approved in USFDA and MHRA

Above decision was communicated to the Health Task Force for guidance. Health Task force has allowed to proceed as per decision of Registration Board as these cases have been endorsed for second time in 297th meeting of the Registration Board. Accordingly, registration letters of Esomeprazole + Naproxen Tablet and Cemitidine 800mg Tablet were issued.

Decision: Keeping in view the above facts, Registration Board deliberated and discussed the case in detail and decided as under:

a. **Sr. No. 01-03 and 12-15: Endorsed its decision regarding grant of registration**
b. **Sr. No. 05-11: Referred the products to Pakistan Chest Society for evaluation of therapeutic value with respect to the quality, safety and efficacy of cough and cold preparations.**
c. **S.No. 04 : Not recomended as amount of Iron in formulation is beyond the UL limits .and advised to place case before Registration Board for further deliberation**
d. **S.No. 16: Not recomended as product is not avaialbel in RRA and advised to place case before Registration Board for further deliberation**
e. **Advised Pharmaceutical Evaluation and Registration Division to inform C&P Division in reponse to their letter**

S No.	Product Name/Formulation
1.	**Multivitamin Syrup (ICI Pakistan)**
2.	**Neurobion Injection (M/s Martin Dow Marker Ltd)**
3.	**Theragran-M tablets (M/s GSK Pakistan LTD)**
4.	**Theragran-H tablets (M/s GSK Pakistan LTD)**
5.	**Dextromethorphan Hydrobromide + Diphenhydramine hydrochloride + Pseudoephedrine hydrochloride cough Syrup (M/s. Zafa Pharma)**
6.	**Reltus DM liquid (M/s Pharmatec Pakistan)**
7.	**Reltus C&F Syrup (M/s Pharmatec Pakistan)**
8.	**Reltus C&F Tablet (M/s Pharmatec Pakistan)**
9.	**Cofcol tablet (M/s. Abbott)**
10.	**Adicos-M Syrup (M/s. Zafa)**
11.	**Adicos-M Syrup (Zafa)**
12.	**Trimebutine Maleate tablet 200mg**
13.	**Trihexyphenidyl HCL tablet 2mg**
14.	**Paracetamol + Caffeine Tablet**
15.	**Buscopan Plus tablets (M/s Martin Dow Marker LTD)**
16.	**Cartigen/Jovit tablets (M/s Getz Pharma)**

Case No.14 Request of M/s. Pharman Pharmaceuticals (Pvt.) Ltd., Gujranwala for import of Controlled Drug Substance for Trial/ Development & Stability Purposes.

M/s. Pharman Pharmaceuticals (Pvt.) Ltd., Gujranwala has requested for permission to import a controlled drug substance for developing their products and stability study. Firm does not have approval of Tablet (Psychotropic) Section and firm has submitted an under taking stating that "When they will go for commercial product manufacturing, they will follow prevailing rules and regulations associated with controlled product manufacturing". Firm has also submitted fee of Rs.7500/0- per product. Details are as under:

1. **Alprazolam**

Sr. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE

1.	FARM-ALP(Alprazolam) 0.5mg tablet	19.5g	CENTAUR PHARMACEUTICALS PVT. LTD. Address: Centaur House Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai-400 055, India.
2.	FARM-ALP (Alprazolam) 1mg tablet	19g	
3.	FARM-ALP (Alprazolam)2mg tablet	38g	
	Total	**76.5g**	
4.	Alprazolam Working Standard	500mg	
5.	USP Alprazolam RS	20mg (1 Vial)	**USP**
6.	USP Alprazolam Related Compound A RS	20mg (1 Vial)	
7.	USP 2-Amino-5-chlorobenzophenone RS	20mg (1 Vial)	
8.	USP Chlorodiazepoxide Related Compound A RS	20mg (1 Vial)	
9.	USP Nordazepam RS	20mg (1 Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. <u>Alprazolam 0.5mg</u>

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	FARM-ALP 0.5mg tablet	Alprazolam	0.5 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)		2g (t) + 7.5g(s) = 9.5g	10	19.5 g
				Batch Size for Stability Batch 2 (5000 tablets)			Chemical testing: 5g Retention Sample: 5g	
				Batch Size for Stability Batch 3 (5000 tablets)				

ii. <u>Alprazolam 1mg</u>

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required

2.	FARM-ALP 1mg tablet	Alprazolam	1 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)		4g (t) + 15g(s) = 19g	-	19 g
				Batch Size for Stability Batch 2 (5000 tablets)				
				Batch Size for Stability Batch 3 (5000 tablets)				

iii. <u>Alprazolam 2mg</u>

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
3.	FARM-ALP 2 mg tablet	Alprazolam	2 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)		8g (t) + 30g(s) = 38g	-	38 g
				Batch Size for Stability Batch 2 (5000 tablets)				
				Batch Size for Stability Batch 3 (5000 tablets)				

2. <u>Bromazepam</u>

Sr. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE
1.	Bromopam (Bromazepam) 3mg Tablet	67g	CENTAUR PHARMACEUTICALS PVT. LTD. Address: Centaur House Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai-400 055, India.
Total		**67g**	
2.	Bromazepam Working Standard	500mg	
3.	BP Bromazepam RS	20mg (1 Vial)	**BP**
4.	BP (2-amino-5-bromophenyl)(pyridin-2-yl)methanone. RS	20mg (1 Vial)	
5.	BP N-[4-bromo-2-(pyridin-2-ylcarbonyl)phenyl]-2-Chloroacetamide. RS	20mg (1 Vial)	
6.	BP 7-bromo-5-(6-methylpyridin-2-yl)-1,3-dihydro-2H-l,4-benzodiazepin-z-one. RS	20mg (1 Vial)	
7.	BP 3-amino-6-bromo-4-(pyridin-2-yl)quinolin-2(1H)-one, RS	20mg (1 Vial)	
8.	BP 2-bromo-N-[4-bromo-2-(pyridin-2-ylcarbonyl)phenyl] acetamide. RS	20mg (1 Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. <u>Bromazepam 3mg</u>

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
						For formulation Development	For QC Testing	Total
1.	Bromopam 3mg Tablet	Bromazepam	3 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	g	g	g
				Batch Size for Trial Batch 2 (2000 tablets)				
				Batch Size for Stability Batch 1 (5000 tablets)		12g (t) + 45g(s) = 57g	10	67 g
				Batch Size for Stability Batch 2 (5000 tablets)			Chemical testing: 5g Retention Sample: 5g	
				Batch Size for Stability Batch 3				

				(5000 tablets)				

3. Lorazepam

Sr. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE
1.	Loram (Lorazepam) 2mg Tablet	48g	CENTAUR PHARMACEUTICALS PVT. LTD. Address: Centaur House Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai- 400 055, India.
Total		**48g**	
2.	Lorazepam Working Standard	500mg	
3.	USP Lorazepam RS	20mg (1 Vial)	**USP**
4.	USP (2-amino-5-chlorophenyl)(2-chlorophenyl)methanone. RS	20mg (1 Vial)	
5.	USP (3RS)-7 -chloro-5-(2-chlorophenyl)-2-oxo-2,3-dihydro-1H-1,4-benzodiazepin-3-yl acetate. RS	20mg (1 Vial)	
6.	USP 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-2H-l,4- benzodiazepin-z-one 4-oxide, RS	20mg (1 Vial)	
7.	USP 5RS)-7 -chloro-5-(2-chlorophenyl)-4,5-dihydro-lH-l,4- benzodiazepine-2,3-dione RS	20mg (1 Vial)	
8.	USP 6-chloro-4-(2-chlorophenyl)quinazoline-2-carbaldehyde. RS	20mg (1 Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Lorazepam 2mg

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	Loram 2mg Tablet	Lorazepam	2 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)			10	

				Batch Size for Stability Batch 2 (5000 tablets)		8g (t) + 30g(s) = 38g	Chemical testing: 5g Retention Sample: 5g	48 g
				Batch Size for Stability Batch 3 (5000 tablets)				

4. Diazepam

Sr. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE
1.	DiaFam(Diazepam) 2mg Tablet	48g	CENTAUR PHARMACEUTICALS PVT. LTD. Address: Centaur House Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai-400 055, India.
2.	DiaFam(Diazepam) 5mg Tablet	95g	
3.	DiaFam(Diazepam) 10mg Tablet	190g	
Total		**333g**	
4.	Diazepam Working Standard	500mg	
5.	USP Diazepam RS	20mg (1 Vial)	**USP**
6.	USP Diazepam Related Compound A RS 2-Methylamino-5-chlorobenzophenone.	20mg (1 Vial)	
7.	USP Diazepam Related Compound BRS 3-Amino-6-chloro-l-methyl-4-phenylcarbostyril.	20mg (1 Vial)	
8.	USP Nordazepam RS 7-Chloro-l,3-dihydro-5-phenyl-2H-l,4-benzodiazepine 2-one	20mg (1 Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Diazepam 2mg

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	DiaFam 2mg Tablet	Diazepam	2 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)			10	48 g

				Batch Size for Stability Batch 2 (5000 tablets)		8g (t) + 30g(s) = 38g		
				Batch Size for Stability Batch 3 (5000 tablets)			Chemical testing: 5g Retention Sample: 5g	

ii. Diazepam 5mg

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
2.	DiaFam 5mg Tablet	Diazepam	5 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)		20g (t) + 75g(s) = 95g	N/A	95 g
				Batch Size for Stability Batch 2 (5000 tablets)			Same lot will be used.	
				Batch Size for Stability Batch 3 (5000 tablets)				

iii. Diazepam 10mg

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
3.	DiaFam 10mg Tablet	Diazepam	10 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g

				Batch Size for Stability Batch 1 (5000 tablets)	Batches (3)	40g (t) + 150g(s) =190 g	N/A	190 g
				Batch Size for Stability Batch 2 (5000 tablets)			Same lot will be used.	
				Batch Size for Stability Batch 3 (5000 tablets)				

5. Clonazepam

Sr. No.	PRODUCT NAME	QUANTITY REQUIRED	SOURCE
1.	CLOFAM(Clonazepam) 0.5mg Tablet	19.5g	CENTAUR PHARMACEUTICALS PVT. LTD. Address: Centaur House Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai-400 055, India.
2.	CLOFAM(Clonazepam) 1mg Tablet	19g	
3.	CLOFAM(Clonazepam) 2mg Tablet	38g	
Total		**76.5g**	
4	Clonazepam Working Standard	500mg	
5	USP Clonazepam RS	20mg (1 Vial)	**USP**
6	USP ClonazepamRelated Compound A RS 3-Amino-4-(2-chlorophenyl)-6-nitrocarbostyril.	20mg (1 Vial)	
7	USP Clonazepam RelatedCompound B RS 2-Amino-2'-chloro-5-nitrobenzophenone	20mg (1 Vial)	
8	USP Clonazepam RelatedCompound C RS 2-Bromo-2'-(2-chlorobenzoyl)-4'-nitroacetanilide	20mg (1 Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Clonazepam 0.5mg

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
1.	CLOFAM 0.5mg Tablet	Clonazepam	0.5 mg	Batch Size for Trial Batch 1 (2000 tablets)		For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)	Trial Batches (2) + Stability	g	g	g

				Batch Size for Stability Batch 1 (5000 tablets)	Batches (3)	2g (t) + 7.5g(s) = 9.5g	10	19.5g
				Batch Size for Stability Batch 2 (5000 tablets)			Chemical testing: 5g Retention Sample: 5g	
				Batch Size for Stability Batch 3 (5000 tablets)				

ii. Clonazepam 1mg

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
2.	CLOFAM 1 mg Tablet	Clonazepam	1 mg	Batch Size for Trial Batch 1 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	For formulation Development	For QC Testing	Total
				Batch Size for Trial Batch 2 (2000 tablets)		g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)		4g (t) + 15g(s) = 19g	N/A	19 g
				Batch Size for Stability Batch 2 (5000 tablets)			Same lot will be used.	
				Batch Size for Stability Batch 3 (5000 tablets)				

iii. Clonazepam 2mg

Sr. No.	Product	API	Mg/Tab	No. of Tab/batch	No. of batches	Quantity of API required		
3.	Clofam 2 mg tablet	Clonazepam	2 mg	Batch Size for Trial Batch 1		For formulation Development	For QC Testing	Total

				(2000 tablets)				
				Batch Size for Trial Batch 2 (2000 tablets)	Trial Batches (2) + Stability Batches (3)	g	g	g
				Batch Size for Stability Batch 1 (5000 tablets)		8g (t) + 30g(s) = 38g	N/A	38 g
				Batch Size for Stability Batch 2 (5000 tablets)			Same lot will be used.	
				Batch Size for Stability Batch 3 (5000 tablets)				

6. Phenobarbitione

S. No.	Product Name/Controlled Drug Substance/Fee Detail	Quantity Required for Trial/Stability Batches	Source
1.	PHENOFAM(Phenobarbitone)BP Syrup: Each 5 ml Contains: Phenobarbitone BP……20mg	101.2g	Nantong Jinghua Pharmaceuticals Co. Ltd. No20, 3 Haibin Road Yanhai Economic Development Zine, Rudong, Nantong Jinghua China.
Total		**101.2g**	
2.	Phenobarbitone Working Standard	500mg	
3.	BP Phenobarbitone RS	20mg (1 Vial)	**BP**
4.	BP (5RS)-5-ethyl-2,6-diimino-5-phenyltetrahydropyrimidin-4 (lH)-one RS	20mg (1 Vial)	
5.	BP (5RS)-5-ethyl-6-imino-5-phenyldihydropyrimidine-2,4 (lH,3H)-dione RS	20mg (1 Vial)	
6.	BP 5-methyl-5-phenylpyrimidine-2,4,6(1H,3H,5H)-trione RS	20mg (1 Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Phenobarbitone 20mg/5ml

Sr. No.	Product	API	Mg/ 120ml bottle	No. of 120ml bottles/ batch	No. of batches	Quantity of API required		
1.	PHENOFAM syrup:	Phenobarbitone	480mg	Batch Size for Trial Batch 1		For formulation Development	For QC Testing	Total

	Each 5ml Contains: Pheno Barbitone BP…20mg			(20 Bottles)	Trial Batches (2) + Stability Batches (3)			
				Batch Size for Trial Batch 2 (20 Bottles)		g	g	g
				Batch Size for Stability Batch 1 (50 Bottles)		19.2 g (t) + 72g(s) = 91.2g	10	101.2 g
				Batch Size for Stability Batch 2 (50 Bottles)			Chemical testing: 5g Retention Sample: 5g	
				Batch Size for Stability Batch 3 (50 Bottles)				

7. Pseudoephedrine

S. No.	Product Name/Controlled Drug Substance/Fee Detail	Quantity Required for Trial/Stability Batches	Source
1.	FAMODEX (Pseudoephedrine) USP Syrup: Each 5 ml Contains: Pseudoephedrine USP…30mg	146.8 g	CENTAUR PHARMACEUTICALS PVT. LTD. Address: Centaur House Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz (E), Mumbai-400 055, India.
Total		146.8 g	
2.	Pseudoephidrene Working Standard	500mg	
3.	USP Pseudoephidrene RS	20mg (1 Vial)	**USP**
4.	USP Pseudoephedrine Hydrochloride RS	20mg (1 Vial)	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

i. Pseudoephedrine 30mg/5ml

Sr. No.	Product	API	Mg/ 120ml bottle	No. of 120ml bottles/ batch	No. of batches	Quantity of API required		
1.	FAMODEX Each 5 ml Contains:	Pseudoe phedrine	720mg	Batch Size for Trial Batch 1 (20 Bottles)		For formulation Development	For QC Testing	Total

	Pseudoephedrine USP…30mg			Batch Size for Trial Batch 2 (20 Bottles)	Trial Batches (2) + Stability Batches (3)	g	g	g
				Batch Size for Stability Batch 1 (50 Bottles)		28.8 g (t) + 108g(s) = 136.8g	10	146.8g
				Batch Size for Stability Batch 2 (50 Bottles)			Chemical testing: 5g Retention Sample: 5g	
				Batch Size for Stability Batch 3 (50 Bottles)				

Decision: Registration Board decided as under:

i. **Recommended the allocation of controlled drug substance(s) i.e., i) Alprazolam ii) Bromazepam iii) Lorazepam iv) Diazepam v) Clonazepam vi) Phenobarbitone and vii) Pseudoephedrine along-with their reference standard(s) and related compound(s) for trial, development & stability batches of above-mentioned products.**

ii. **The firm shall be advised to maintain records of used substances and waste materials having above APIs and same shall be destroyed after approval of Controlled Drugs Division, DRAP.**

iii. **Marketing Authorization to M/s. Pharman Pharmaceuticals (Pvt.) Ltd., Gujranwala shall be granted as per applicable policy regarding Psychotropic / Narcotic sections.**

iv. **Authorized Chairman Registration Board for disposal of all types of cases where approval/ recommendation of Registration Board is required for procurement of controlled drug substances/ innovator's drug product pack/ reference and impurity standards etc. for trial/ development & stability purposes.**

Case No. 01: Change in registration status of products from Bulk Import Local Repacking to Local Manufacturing applied by M/s Martin Dow Limited, Karachi.

M/s Martin Dow Limited, Karachi applied for change in registration status of their registered products Alemed Injection 5mg/5ml
(Reg. No. 001049) from bulk import local repack to local manufacturing as per following details:

3.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13845 dated 08.06.2022 Dy No 25716 dated 12.09.2022
	Details of fee submitted	PKR 75,000/-: dated 03.06.2022
	The proposed proprietary name / brand name	**Rivotril Tablets 0.5mg** **(Reg No 001049)** Last renewal dated **13.04.2020**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains Clonazepam…… 0.5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Benzodiazepines
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	50’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by USFDA KLONOPIN 0.5mg TABLET’’ manufactured by CHEPLAPHARM ARZNEIMITTEL GMBH
	For generic drugs (me-too status)	Tovir 0.5mg Tablets by Adamjee Pharmaceuticals Pvt. (Registration No. : 080335)
	GMP status of the Finished product manufacturer	GMP inspection conducted on 20.10.2021 Tablet (psychotropic) section approved on 30.07.2018
	Name and address of API manufacturer.	F.I.S. –Fabbrica Italiana Sintetici S.p.A. **Address:** *Site of Montecchio Maggiore*

<table>
<tr><td></td><td></td><td>DUNS# 431189117
Viale Milano, 26
36075 Montecchio Maggiore (VI) –
Italy</td></tr>
<tr><td></td><td>Module-II (Quality Overall Summary)</td><td>Firm has submitted QOS details as per WHO QOS PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance and drug product is submitted.</td></tr>
<tr><td></td><td>Module III (Drug Substance)</td><td>The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance</td></tr>
<tr><td></td><td>Stability studies</td><td>Stability study conditions:
Real time: 30 ± 2°C / 75 ± 5% RH for 60 months
Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months
Batch No MIX 9200001-222
MIX 9200001-223
MIX 9200001-224</td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.</td></tr>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Pharmaceutical Equivalence have been established against the Innovator product that is Rivotril 0.5mg Tablet manufactured by Recipharm Leganes S.L.U., Spain by performing quality tests (Identification, Assay, Dissolution, weight variation and impurity testing.).
CDP has been performed against the same brand that is Rivotril 0.5mg Tablet manufactured by Recipharm Leganes S.L.U., Spain as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Martin Dow</th></tr>
<tr><td>Brand name</td><td>Rivotril 0.5mg Tablet</td><td>Rivotril 0.5mg Tablet</td></tr>
<tr><td>Batch No.</td><td>E2490</td><td>NPD-T-1877-S</td></tr>
</table>
</td></tr>
</table>

		Comparative dissolution studies have been performed in following mediums: 1. pH 1.2 0.1N HCl 2. pH 4.5 Acetate buffer 3. pH 6.8 Phosphate buffer The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		F.I.S. –Fabbrica Italiana Sintetici S.p.A. *Site of Montecchio Maggiore* DUNS# 431189117 Address: Viale Milano, 26 36075 Montecchio Maggiore (VI) –Italy		
API Lot No.		201909300384		
Description of Pack (Container closure system)		Tablets are packed in Alu/PVC blisters of 10's packed in unit carton		
Stability Storage Condition		Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		NPD-T-1871-S	NPD-T-1877-S	NPD-T-1878-S
Batch Size		1500 tablets	5000 tablets	5000 tablets
Manufacturing Date		11.02.2022	15.02.2022	15.02.2022
Date of Initiation		25.02.2022	25.02.2022	25.02.2022
No. of Batches		03		
Administrative Portion				
49.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Pirfedow Tablets 267mg which was approved in 297th Meeting of Registration Board held on 12th – 15th January 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.		
50.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate for F.I.S. –Fabbrica Italiana Sintetici S.p.A. issued by Italian Medicines Agency (Agenzia italiana del farmaco) based on inspection conducted on **26-09-2019** extended till the end of 2022.		

51.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice no. 2102090 RL dated: 10-12-2021 to import Clonazepam 0.092 Kgs for trial and development purpose. License to import drug for trial batch No 196/DRAP dated 28.12.2021
52.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
53.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
54.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator (AD PEC-XX):

- **1.6.5** Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin is provided.
- Tablet (Psychotropic) Section approval letter No. F. 2-6/86-Lic (Vol-VI) dated 14-04-2022 issued by Licensing Division.

4.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 13846 dated 08.06.2022 Dy. No 25717 dated 12.09.2022
	Details of fee submitted	PKR 75,000/-: dated 03.06.2022
	The proposed proprietary name / brand name	**Rivotril Tablets 2mg** **(Reg No 003626)** Last renewal dated 13.04.2020
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains Clonazepam 2mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Benzodiazepines
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30's & 100's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by USFDA KLONOPIN 0.5mg TABLET'' manufactured by CHEPLAPHARM ARZNEIMITTEL GMBH
	For generic drugs (me-too status)	Tovir 2mg Tablets by Adamjee Pharmaceuticals Pvt. (Registration No. : 080336)
	GMP status of the Finished product manufacturer	GMP inspection conducted on 20.10.2021 Tablet (psychotropic) section approved on 30.07.2018
	Name and address of API manufacturer.	F.I.S. –Fabbrica Italiana Sintetici S.p.A. **Address:** *Site of Montecchio Maggiore* DUNS# 431189117 Viale Milano, 26 36075 Montecchio Maggiore (VI) – Italy
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, characterization, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30 ± 2°C / 75 ± 5% RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months Batch No MIX 9200001-222 MIX 9200001-223 MIX 9200001-224
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

<table>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Pharmaceutical Equivalence have been established against the Innovator product that is Rivotril 2mg Tablet manufactured by Recipharm Leganes S.L.U., Spain by performing quality tests (Identification, Assay, Dissolution, weight variation and impurity testing.).
CDP has been performed against the same brand that is Rivotril 2mg Tablet manufactured by Recipharm Leganes S.L.U., Spain as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Martin Dow</th></tr>
<tr><td>Brand name</td><td>Rivotril 2mg Tablet</td><td>Rivotril 2mg Tablet</td></tr>
<tr><td>Batch No.</td><td>E1845</td><td>NPD-T-1879-S</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:

1. pH 1.2 0.1N HCl
2. pH 4.5 Acetate buffer
3. pH 6.8 Phosphate buffer

The values for f1 and f2 are in the acceptable range.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.</td></tr>
</table>

<table>
<tr><th colspan="4">STABILITY STUDY DATA</th></tr>
<tr><td>Manufacturer of API</td><td colspan="3">F.I.S. –Fabbrica Italiana Sintetici S.p.A.
Site of Montecchio Maggiore
DUNS# 431189117
Address:
Viale Milano, 26
36075 Montecchio Maggiore (VI) –Italy</td></tr>
<tr><td>API Lot No.</td><td colspan="3">201909300384</td></tr>
<tr><td>Description of Pack (Container closure system)</td><td colspan="3">Tablets are packed in Alu/PVC blisters of 10’s packed in unit carton</td></tr>
<tr><td>Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td>Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 6 months</td></tr>
<tr><td>Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td>Batch No.</td><td>NPD-T-1872-S</td><td>NPD-T-1879-S</td><td>NPD-T-1880-S</td></tr>
<tr><td>Batch Size</td><td>1500 tablets</td><td>5000 tablets</td><td>5000 tablets</td></tr>
<tr><td>Manufacturing Date</td><td>11.02.2022</td><td>16.02.2022</td><td>16.02.2022</td></tr>
<tr><td>Date of Initiation</td><td>25.02.2022</td><td>25.02.2022</td><td>25.02.2022</td></tr>
<tr><td>No. of Batches</td><td colspan="3">03</td></tr>
<tr><th colspan="4">Administrative Portion</th></tr>
</table>

55.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Pirfedow Tablets 267mg which was approved in 297th Meeting of Registration Board held on 12th – 15th January 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
56.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate for F.I.S. –Fabbrica Italiana Sintetici S.p.A. issued by Italian Medicines Agency (Agenzia italiana del farmaco) based on inspection conducted on **26-09-2019** extended till the end of 2022.
57.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice no. 2102090 RL dated: 10-12-2021 to import Clonazepam 0.092 Kgs for trial and development purpose. License to import drug for trial batch No 196/DRAP dated 28.12.2021. Ministry of Narcotics Control Approval Letter No. 15-12/2021-CS dated 22-02-2022 for grant of NOC for manufacturing/ registration/ quota allocation of Controlled Substances (Permit No. 783/2022).
58.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
59.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
60.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator (AD PEC-XX): • **1.6.5** Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance / API manufacturer issued by concerned regulatory authority of country of origin is provided. • Tablet (Psychotropic) Section approval letter No. F. 2-6/86-Lic (Vol-VI) dated 14-04-2022 issued by Licensing Division.		

Decision: Registration Board approved the registration status of Rivotril Tablets 0.5mg (Reg No 001049) & Rivotril Tablets 2mg (Reg No 003626) from bulk import, local repacking to local manufacturing by M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi.

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

Case No. 01: M/s. Hamaz Pharmaceuticals Pvt Ltd., 13km Bosan Road, Lutfabad, Multan.

M/s Hamaz Pharmaceuticals Pvt. Ltd., Multan has submitted the application for following correction in their formulation:

1.	021324	Skymox Forte Syrup Each 5ml contains:- Amoxycillin Trihydrate eq. to Amoxycillin Base… 250mg	Skymox Forte Suspension	15-05-1998 **Last renewal** 09-05-2018	Fee Rs 30,000/- deposited dated 06-07-2022 R&I Dy. No. 19845 dated 06-07-2022
2.	008184	Skymox Dry Syrup Each 5ml contains:- Amoxycillin Trihydrate eq. to Amoxycillin Base… 125mg	Skymox Suspension	24-05-1997 **Last renewal** 14-04-2022	Fee Rs 30,000/- deposited dated 06-07-2022 R&I Dy. No. 19846 dated 06-07-2022

The case was considered by PRVC and referred to Registration Board as follows:
"The Committee deferred the case and advised to place before Registration Board for discussion on the dosage form mentioned on label of Amoxil Syrup."

It is pertinent to mention that the Innovator drug product is in also Suspension formulation and brand leader in Pakistan i.e. Amoxil of M/s GSK Pakistan, Karachi has also approval of oral suspension.

Decision: Registration Board approved the request of the firm for correction in dosage form of above products from Syrup to Oral Suspension.

Case No. 2: M/s. Lahore Chemical & Pharmaceuticals Works Pvt Ltd., 137 Shahrah Maulana Jalaludin Roomi, Lahore.

M/s. Lahore Chemical & Pharmaceuticals Works Pvt Ltd has submitted application for resemblance / similarity of brand name Pulvilox Tablet Reg. No. 041318 of M/s Hansel Pharmaceuticals (Pvt.) ltd., Lahore with registered **Pulvilox Tablet 250mg, 500mg Reg. No. 069469 & Reg. No. 069470** of **M/s. Lahore Chemical & Pharmaceuticals Works Pvt Ltd., Lahore**.

In this context, it is submitted that the brand Pulvilox was issued first to M/s. Hansel Pharma on **28-02-2013**. Later on, M/s Hansel Pharmaceuticals issued NOC to transfer the brand name in name of M/s Master Pharma (Pvt.) Limited and surrendered all/ any rights of ownership of the said brand. However, the said brand name was never issued in name of M/s Master Pharmaceuticals (Pvt.) Ltd.

Later on, the same brand name was issued to M/s Lahore Chemical & Pharmaceutical Work (Pvt.) Ltd., Lahore against their request of brand name change of registered products **Levopath 250mg (Reg. No. 069469) & Levopath 500mg (Reg. No. 069470) on 04-05-2016.** Accordingly, a letter was issued to M/s Hansel Pharma for change in brand name as they had already surrendered the rights in favor of M/s Master Pharma.

Now, M/s Hansel Pharmaceuticals (Pvt.) Ltd. has submitted a copy of letter No. F. 5-180/2013-Reg. V dated 14-10-2016 issued by then DDC Reg. V advising M/s Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd., Lahore to stop the production of said brand and apply for change in brand name. Moreover, M/s Hansel Pharma submitted that they have supply agreement with Master Pharma to transfer ownership in respect of the mentioned brand name when Master Pharma develop their own manufacturing facility and Master Pharma did not fulfill that requirement. Futhermore, under the agreement NOC to Master Pharma cannot use that brand name to manufacturer its product (Contract & Toll Manufacturing) from other manufacturer.

The case was considered in 88th meeting of PRVC wherein the Committee decided as follows:

"The Committee deferred the case and advised to place the case before Registration Board for discussion."

Decision: Registration Board referred the case for legal opinion on the use of same brand name with two companies on the basis of following details:

i. **M/s Hansel Pharmaceuticals (Pvt.) Ltd., Lahore is marketing their product with brand name *"Pulvilox"*, while they had already surrendered all/ any rights of ownership of the said brand to M/s Master Pharma (Pvt.) Limited. It is pertinent to mention here that M/s Master Pharma (Pvt.) Ltd. is neither a licensed manufacturer nor it has ever applied for said brand name.**

ii. **M/s Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd., Lahore is also marketing their product with brand name *"Pulvilox"*, while initially this brand name was issued to M/s Hansel Pharmaceuticals (Pvt.) Ltd., Lahore and M/s Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd., Lahore had already been advised to change the brand name vide letter No. F. 5-180/2013-Reg. V dated 14-10-2016.**

Case No. 3: M/s Pharmix Laboratories (Pvt.) Ltd., Lahore.

M/s Pharmix Laboratories (Private) Limited, Lahore submitted that they are manufacturer and exporter of Ulcofin (Oral Liquid Suspension) with registration number 053752. DRAP issued a letter for suspension of Famotidine (Oral Liquid Suspension) to suspend all registrations of Famotidine suspension but the name of Pharmix Laboratories was not in that list. The firm further submitted that they tried their best to submit appeal against the decision and deposited fee of Rs. 50,000/- but their appeal was not received as their name was not included in the list. The firm further submitted that they are exporting their products and Appellate Board has already allowed oral liquid formulations, hence, the firm requested to issue them suspension letter in light of decision of 317th meeting, so that they can submit their appeal to Appellant Board.

In this context, it is submitted that Ulcofin Suspension 10mg (Reg. No. 053752) was registered in name of M/s Pharmix Laboratories as liquid suspension. Registration Board in its 250th meeting while considering another case of such formulation, decided as follows:

- *Applicants shall revise their formulation as per innovator (new registration application with complete fee) within six months if manufacturing facility is approved by CLB.*
- *For already registered drugs, same procedure as mentioned above (at Sr. No. i) shall be adopted. Otherwise show cause notice shall be issued for de-registration of registered drugs in this formulation.*
- *All such application shall be processed on priority basis."*

Accordingly, the firm in 2017 applied for the standardization of formulation as per reference regulatory authority and duplicate dossier in January, 2022. The application was discussed in 317th meeting along with other cases of Famotidine and a suspension letter was issued to the registration holders of Famotidine liquid suspension. However, as the firm had already applied for standardization of formulation, therefore, the suspension letter was not issued to the firm and the firm could not file the appeal. Now, as the Appellate Board has allowed resumption of sale and manufacturing of Famotidine liquid suspensions only for the firms who were in appeal before Appellate Board and as the firm could not submit the appeal as noted above, therefore, now the firm is requesting to issue them suspension letter, so that they can file the appeal before Appellate Board.

Decision: Registration Board deliberated the matter in details and decided to refer the case for legal opinion on the request of the firm for resumption of manufacturing and sale of Ulcofin Suspension 10mg (Reg. No. 053752) on the basis of above details.

Case No.01: Registration of Drug (s) of M/s Pharmasol (Pvt.) Ltd, Plot No. 549, Sunder Industrial Estate, Lahore, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-17/2005-Lic dated 22-12/2017
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 22-08-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Garakal Infusion Each 100ml contains: L-Arginine HCl..... 4.2gm Levocarnitine.....2gm	Purchase order from Uzbekistan	Dy. No. 8350 (29.09.2022) Rs.75,000/- (27.09.2022)
2.	Garakarnit Infusion Each 100ml contains: L-Carnitine.....2g	Purchase order from Uzbekistan	Dy. No. 8351 (29.09.2022) Rs.75,000/- (27.09.2022)
3.	Garakarnit Injection Each 5ml contains: L-Carnitine.....2g	Purchase order from Uzbekistan	Dy. No. 8352 (29.09.2022) Rs.75,000/- (27.09.2022)

Decision: Registration Board approved request of the firm for registration of above mentioned products for Export Purpose Only. Since applied formulations are neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No.02: Registration of Drug (s) of M/s Scotmann Pharmaceuticals, Plot No. 5-D, I-10/3, Islamabad, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Inspection renewal of DML dated 22-11/2018

GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 09-11-2020
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Livia Dry Suspension 10mg Each ml contains: Active Ingredient: Sildenafil (as citrate).....10mg	Purchase order from Afghanistan	Dy. No. 8299(28.09.2022) Rs.75,000/- (09.09.2022)

Decision: Registration Board deferred the case as the matter of registration of Sidenafil containing formulations is under consideration of Policy Board of DRAP.

Case No.03: Registration of Drug (s) of M/s Wnsfield Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Inspection renewal of DML dated 18-01/2018
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 10-12-2020
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Paramine Sachet Each Sachet contains: Paracetamol.....125mg Chlorpheniramine Maleate.....0.25mg Ascorbic Acid.....67mg	Purchase order from Cambodia	Dy. No. 8447(03.11.2022) Rs.75,000/- (27.10.2022)
2.	Parawin Sachet Each Sachet contains: Paracetamol.....325mg Chlorpheniramine Maleate.....2mg Thiamine Nitrate.....10mg	Purchase order from Cambodia	Dy. No. 8446(03.11.2022) Rs.75,000/- (27.10.2022)

Decision: Registration Board approved request of the firm for registration of above mentioned products for Export Purpose Only. Since applied formulations are neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th

meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

DEFERRED CASE 78TH PRVC

Case No.01: Registration of Drug(s) of M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road, Lahore Exclusively for Export Purpose.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements as Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form-5; (Page No.1218–1226/C).
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML (P.No.1227/C). Approval of concerned Sections confirmed from issuance of DML dated 23-January-2019 (P.No.1228/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP Status/ application submitted by firm for issuance dated 16-November-2021 (P.No.1229/C)
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (P.No.1231-1232/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(R&I)/Fee with date
I	II	III	IV
1.	Ferroplex 40mg Injections Each ml contains: Activated Vitamin B12 (injectable raw liver, N.F. 2mcg/ml) Equivalent to Cyanocobalamin……...…….0.20mcg Vitamin C……...……5.00mg Vitamin B12 (Cyanocobalamin)……500.00mcg Ferrous Citrate…….....….0.02g Panthenol (B5)……...…….3.00mg Thiamine HCl (B1)……..……..50.00mg Riboflavin (B2)……...……0.60mg Pyridoxine HCl (B6)……...……3.00mg Niacinamide (B3)…….…….45.00mg Choline Chlorhydrate…….……6.00mg Inositol…….……..6.00mg	Mexico Approved Formulation	Dy. No.7578/22 (07.04.2022) Rs.75,000/- (11.03.2022)

Remarks: Above mentioned formulation has been added in Red List i.e. List of Firms and their products subject to detention without physical examination.

Decision of PRVC: The Committee evaluated the case and deferred the request of firm for approval status in RRA.

The FDA Red List is for specific products and firms and is not a generalized list. Moreover, **t**he firm has submitted the copy of Purchase order of 2000 Injections form Egypt.

Decision: Registration Board approved the request of the firm for registration of product for Export Purpose Only. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

1. Change of Primary Packaging Material of Drug(s) of M/s. ICI Pakistan Ltd. S-33, Hakes Bay Road SITE Karachi.(Page No.0-0/C).

M/s. ICI Pakistan Ltd Karachi, has requested for change in primary packaging material of their following registered product details are as under:

Sr.#	Reg. No.	Name of Product with composition	Existing Packaging	Proposed Packaging
1.	097003	Citralka Liquid Each 5ml contains: Disodium hydrogen citrate……1.351g	Amber Glass Bottle	Amber PET Bottle

Firm has submitted the following documents as per SOP (approved in 283rd meeting).

Sr.#	Documents Required (as per SOP M-283)	Information Provided
1.	Application with required fee as per relevant SRO.	Fee of Rs.10,000/- dated 18.08.2022 Application dated: 18.08.2022 (R&I DRAP 23389) Reply dated 01.04.2022(R&I DRAP 8554)
2.	Copy of registration letter and last renewal status	Reg. 097003 (dated 28.06.2018) Product transferred from Pfizer Pakistan Limited Karachi site on 17.05.2011 Last renewal dated Nil
3.	Justification of proposed change including data on the suitability of the container-closure system (e.g. extractable/ leachable testing (where applicable), permeation testing, light transmission) demonstrating equivalent or superior protection compared to the current packaging system. For changes to functional packaging related to container closure (e.g. MDIs etc.), data to demonstrate the functioning of the new packaging	Provided
4.	If the container closure system of applied formulation is different from that of the reference product, manufacturer will place first three lab scale batches or developmental scale batches as set by Registration Board in 276th meeting, at 3 months of accelerated and 3months of real time studies for compatibility of applied formulation with container closure system as directed by Pharmacopeia of Reference Regulatory Authorities. Registration Board shall be informed immediately and along with market withdrawal in case of any significant change about result of stability studies	Firm has submitted stability data as follows: **Accelerated studies** (Temp 40◦C±2◦C/ RH 75%±5%) Interval: 0,3,6 months **Long term studies** (Temp 30◦C±2◦C /RH 65%±5%) **Interval**: 0,3,6,9,12,18,24 months **Testing parameters**: Description, pH, Assay, Total Aerobic Microbial Count, Total Yeast & Mold Count,Pathogens **Reference Test Method: Inhouse** **Batch No:** T-04, T-05 & T-06 **Batch size**: 2070 Units
5.	Shelf life of the drug product supported with justification.	Provided
6.	Existing and proposed container closure system with differences (e.g. description, materials of construction of primary packaging components,	Provided

	specifications, if appropriate) highlighted in tabular form.	
7.	If the proposed change requires change in manufacturing section/ facility, then a new registration application with prescribed fee shall be submitted.	Not applicable
8.	An Undertaking that: • To perform stress studies. • In case of any quality complaint/OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. • Provided information is true & correct.	Provided

Decision of 90-PRVC:
"The Committee deferred the case for submission of batch size, evidence of availability of formulation in Amber PET Bottle in RRAs and clarification of performing assay by titration method instead of HPLC method."

Firm's Reply		
S.No.	**Query**	**Response of the firm**
1.	Status in reference regulatory authority	Change of registration status from Pfizer to ICI Pakistan of Citralka was approved by the Registration Board in its 284th meeting based on the confirmation by TGA Australia (copy of DRB decision is attached. RRA of Citralka Liquid in Pet bottle is not available hence reference of Citralka Liquid marketed by Pfizer India in PET bottle is submitted. Due to non-availability of SRA, Primary packing analysis has been provided in addition to the stability studies as submitted in similar cases of mucaine suspension and Ketress syrup.. We would also like to inform that approval for change primary of packing of Registered Drug Ketress syrup was approved by the PRV, Letter No.F.80-PRVC/2022(PR-I)
2.	Trial Batch Size	2070 Units
3.	Rationale for performing titrimetric analysis	Citralka Liquid is tested through titration method since its development by Pfizer Pakistan. At the time of manufacturing site change, ICI Pakistan Limited adopted the same testing method. Analytical method validation performed by ICI Pakistan Limited is also provided.

The firm has also stability data of 24 months.

Decision: Registration Board approved the change in primary packaging of Citralka Liquid (Reg. No. 097003) from Amber Glass Bottle to Amber PET Bottle. The firm shall perform continuous monitoring and in case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to Registration Board and all the stock shall be recalled from the market immediately.

2. Application for permission of secondary packaging of registered products on contract basis applied by M/s Sami Pharmaceuticals (Pvt.) Ltd., Karachi.

M/s Sami Pharmaceuticals (Pvt.) Ltd., F-95, Off Hub River Road, SITE, Karachi applied for permission to conduct secondary packaging of their following registered products on contract basis from their other plant situated at Plot No. F-140/A, SITE, Karachi:

Sr. No.	Reg. No.	Name of Product
1.	067516	ECASIL (Linezolid) 200mg/100ml Infusion
2.	067518	ECASIL (Linezolid) 600mg/300ml Infusion

3.	037711	EFFIFLOX (Levofloxacin) 500mg/100ml IV Infusion
4.	053227	MOFEST (Moxifloxacin HCl) Infusion
5.	012066	NOVIDAT (Ciprofloxacin) 200mg/100ml Injection
6.	042270	NOVIDAT DS (Ciprofloxacin) 400mg/100ml Infusion
7.	053223	PROVAS (Paracetamol) Infusion
8.	097180	UBROF (Ibuprofen) 400mg/100ml Infusion
9.	019704	GRASIL (Amikacin Sulphate) 100mg Injection
10.	014251	GRASIL (Amikacin Sulphate) 500mg Injection

The firm has submitted fee of Rs. 75000/- for each product. Moreover, the firm has informed that the final quality control release will be done by registration holder of above product i.e. M/s Sami Pharmaceuticals (Pvt.) Ltd., F-95, Off Hub River Road, SITE, Karachi.

DRAP Authority while consider the said matter in its 152nd meeting decided as follows:
"The Authority deliberated that packing is part of manufacturing operations and permission to pack a drug on another site, other than the manufacturing site of bulk product, is the purview of Registration Board, therefore, decided to forward the matter to Registration Board for its consideration under Rule 20-A of the Drugs (Licensing, Registration & Advertising) Rules, 1976."

Decision: Registration Board approved the request of the firm for change in secondary packaging site only on contract manufacturing basis for already registered drug products as per following details:

Sr. No.	Reg. No.	Name of Product	Manufacturing, Primary Packaging & Quality Control Release Site	Secondary Packaging Site
11.	**067516**	**ECASIL (Linezolid) 200mg/100ml Infusion**	**M/s Sami Pharmaceuticals (Pvt.) Ltd., F-95, Off Hub River Road, SITE, Karachi.**	**M/s Sami Pharmaceuticals (Pvt.) Ltd., Plot No. F-140/A, SITE, Karachi**
12.	**067518**	**ECASIL (Linezolid) 600mg/300ml Infusion**		
13.	**037711**	**EFFIFLOX (Levofloxacin) 500mg/100ml IV Infusion**		
14.	**053227**	**MOFEST (Moxifloxacin HCl) Infusion**		
15.	**012066**	**NOVIDAT (Ciprofloxacin) 200mg/100ml Injection**		
16.	**042270**	**NOVIDAT DS (Ciprofloxacin) 400mg/100ml Infusion**		
17.	**053223**	**PROVAS (Paracetamol) Infusion**		
18.	**097180**	**UBROF (Ibuprofen) 400mg/100ml Infusion**		
19.	**019704**	**GRASIL (Amikacin Sulphate) 100mg Injection**		
20.	**014251**	**GRASIL (Amikacin Sulphate) 500mg Injection**		

3. Change in status of Product Registration Holder from Drug Manufacturing License (000234) to Drug Sale License without change in manufacturing site.

The application of M/s Bayer Pakistan Limited, Lahore was considered in 320th meeting of RB wherein the Board decided as follows:

DMl Site	**DSL Site**	**Manufacturing Site**
DML No. 000243 Bayer Pakistan Pvt Ltd Plot No. 108, Quaid-e-Azam Industrial Esate, Kot Lakhpat, Lahore Pakistan	DSL No. 01. Bayer Pakistan Pvt Ltd. Plot No. 23 Sector No. 22, Korangi Industrial Area, Karachi 74900, Pakistan	Manufacturing site shall remain same i.e. M/s Novartis pharma, C-21, S.I.T.E Karachi

The products details is as under:

Sr. No.	**Reg. No**	**Name of Product**
1.	107229	Canesten 1, Vaginal Cream with Applicator
2.	107224	Canesten 1 Vaginal Tablet of 0.5g
3.	107225	Canesten 6 Vaginal Tablets of 0.1g
4.	107227	Canesten Clotrimazole Cream
5.	107226	Canesten Extra Bifonazole Cream
6.	111897	Baycuten N Cream
7.	109734	Baydal Tablets

Registration Board decided as follows:

"Registration Board after deliberation deferred the request and advised the firm to explain relevant rule for consideration of the proposed change."

The firm has now submitted the following:

"Reference our previous letters on the subject cited above, we, Bayer Pakistan (Pvt) Ltd like to highlight that, we are established in Pakistan Since (1963) and has been a major player in the healthcare sector of the country for last 59 years and also known as availability of Innovator Products in the Country. The Physicians and patients equally trust our products for treatment of diseases.

During the course of our services to people of Pakistan we established our manufacturing plant in the country but due to global financial situation the parent office has decided to close/divest the manufacturing plant in the country. Some of our products as listed below are already on contract manufacturing at Novartis plant in Karachi.

We are sure that you appreciate that "under Rule 30(5) of Drug (Licensing, Registration & Advertisement) Rules 1976", registration holders are responsible to ensure availability of their registered product. Proviso to same rule states *that in the circumstances beyond the control of a manufacturer, of a drug which may lead to reduction in the production of that drug, the circumstances may be intimated to the Registration Board.*

As a law-abiding company, we brought to your notice that we had applied for permission to continue the contract of these products to ensure availability and we fear that if permission to continue contract manufacturing is not granted than we will be unable to maintain the availability of these vital products and large number of patients are likely to suffer due to shortage of these products.

Following are the Bayer's Innovator products in scope of above said changes. The number of patients that may suffer is also provided in the below table.

Units sold in Pakistan:

2018 -2022 Units sold to consumers in Pakistan

In the period between 2018 and 2022 nearly 20.0 Mio units of Canesten and Baycuten N have been served to consumers in Pakistan.

Name of Products	**Units served 2018-2022 *(IQVIA data 2018-2022)***
BAYCUTEN N CREAM 15 GM	2,253,340
CANESTEN CLOTRIMAZOLE CREAM 10Gm	6,969,417

CANESTEN CLOTRIMAZOLE CREAM 20Gm(Launched in 2022)	653,340
CANESTEN EXTRA BIFANAZOLE CRM 15GM	962,222
CANESTEN VAG. CREAM 5GM WITH APPLICATOR	3,086,387
CANESTEN VAG.TB 0.1G x 6'S	1,617,671
CANESTEN VAG.TB 0.5G x 1'S	4,062,201

*Source:
IQVIA data 2018-2022)

WHO list of essential PRODUCTS.

All products subject to the submitted change are listed in the World Health Organization (WHO) Model List of Essential Medicines (ref. 22nd list from 2021).

Data Of Prescribers and Patients Already Using:

S. No.	Product Details	Reg. No.	Number of Prescribers (Approx.)	Patient Already Using (Approx.)
1	Canesten 1, Vaginal Cream with Applicator	107229	10,200	1,752,000
2	Canesten 1 Vaginal Tablet of 0.5g	107224		
3	Canesten 6 Vaginal Tablets of 0.1g	107225		
4	Canesten Clotrimazole Cream	107227	3,300	334,000
5	Canesten Extra Bifonazole Cream	107226	400	33,000
6	Baycuten N Cream	111897	700	53,000
7	Baydal Tablets	109734	8000	2,572,940

Tender Business for Government/Private Institutes:

Bayer has to provide following stock to the Government institutions, failing this may cause company blacklist.

S. No.	Product Details	Reg. No.	Number of Packs
1	Canesten 1, Vaginal Cream with Applicator	107229	864
2	Canesten 1 Vaginal Tablet of 0.5g	107224	168
3	Canesten Clotrimazole Cream	107227	1980
4	Baydal Tablets	109734	1080

Units sold in Afghanistan: (Export Business)

In the current year of 2022 approx. 4 hundred thousand units of drug manufactured by Novartis Pharma on contract manufacturing have been sold to Afghanistan generating approx. 65million PKR revenue and contributing to the export business of Pakistan.

Year - 2022				
S.#	**Name Of Products**	**Pack Size**	**No Of Packs**	**Value (PKR)**
1	Baydal Tablet	10x10's	134,500	46,524,176

2	BAYCUTEN N CREAM	15G	74,000	4,611,687
3	CCANESTEN CLOTRIMAZOLE CREAM	20gm	74,246	5,989,053
4	Canesten 1 Vaginal Tablet of 0.5g	1 x 1's	9,000	702,596
5	Canesten 6 Vaginal Tablets of 0.1g	1 x 6's	50,372	4,504,147
6	Canesten Extra Bifonazole Cream	1 x 15g	2,000	240,578
7	Canesten 1, Vaginal Cream with Applicator	11 x 5g	29,400	1,998,327

You will also agree that "under Rule 29(8) of Drug (Licensing, Registration & Advertisement) Rules 1986" where it is necessary in the public interest so to do, the Registration Board may even register a drug on its own motion without even having received any application for registration.
We Bayer Pakistan (Pvt) Ltd are of the considered opinion that under the above given powers of the Drug Registration Board and provisions of Rule 20A as amended vide SRO 1347 (I)/2021 can consider the clause "c" (Reproduced below) of the said rules to allow continued manufacturing of the above listed products through contract manufacturing at Novartis Plant based on DSL of Bayer Pakistan (Pvt) Ltd.

As per clause (c), Rule 20A of Drugs (Licensing, Registering and Advertising) Rules, 1976:
"a foreign pharmaceutical company (manufacturer or marketing authorization holder) having drug sale license in Pakistan for their research, innovator, originator drug products or drug products already registered for sale by any of reference regulatory authorities adopted by the Registration Board"

The applied change will ensure continued availability of these quality drugs in best interest of patients. Manufacturing site will also remain the same as already approved by DRAP i.e. Novartis Pharma (Pakistan) Limited (Contract Manufacturer). We ensure maintenance of highest Quality as per Bayer standards."

Decision: **Registration Board deferred the case for opinion of Legal Affairs Division whether clause (c) of Rule 20A of Drugs (Licensing, Registration and Advertising) Rules, 1976 is also applicable for already registered drug products of such firm in Pakistan on its DML and now firm has requested for registration on DSL basis.**

4. Drug products (infusions) seeking approval with Eurocap Cases.

i. M/s. Otsuka Pakistan Ltd, F/4-9, H.I.T.E., Hub, Baluchistan.

M/s Otsuka Pakistan Ltd., Baluchistan applied for change in shape of container closure system with Euro-cap for following products:

1.	018360	Pladex- 5 Injection 1000mL Each 1000mL contains: - Dextrose B.P….. … 50gm LDPE Container (Plabottle) with **middle cap**	Pladex- 5 Injection 1000mL Each 1000mL contains: - Dextrose B.P. . .. … 50gm LDPE Container (Plabottle) with **euro-cap**	Initial date: 05-10-1995 Renewal applied: 01.09.2020	Fee Rs. 10,000/- each deposited on dated 03-03-2022 **<u>Justification</u>: The primary change is only in shape of container closure**
2.	018361	Pladex-10 Injection 1000mL Each 1000mL contains: - Dextrose B.P….. … 100gm LDPE Container (Plabottle) with **middle cap**	Pladex-10 Injection 1000mL Each 1000mL contains: - Dextrose B.P.. .. … 100gm LDPE Container (Plabottle) with **euro-cap**	Initial date: 05-10-1995 Renewal applied: 07.09.2020	

3.	081059	Pladex-25 Injection 1000mL Each 1000mL contains: - Dextrose B.P….. … 250gm LDPE Container (Plabottle) with **middle cap**	Pladex-25 Injection 1000mL Each 1000mL contains: - Dextrose B.P.. .. … 250gm LDPE Container (Plabottle) with **euro-cap**	Initial date: 22-06-2016 Renewal applied: 26.04.2021	**system made from same material LLDPE** Dy.# 647-PR-I, 646, 649, 648, 644, 645, 643& 642. dated 12.04.2022
4.	003031	Plasaline Injection 1000mL Each 1000mL contains: - Sodium Chloride B.P. …….....9.0gm LDPE Container (Plabottle) with **middle cap**	Plasaline Injection 1000mL Each 1000mL contains: - Sodium Chloride B.P… …… … 9.0gm LDPE Container (Plabottle) with **euro-cap**	Initial date: 30-08-1989 Renewal applied: 28.05.2019	
5.	003028	Pladexsal Injection 1000mL Each 1000mL contains: - Dextrose. . …….. … 50gm Sodium Chloride…. 9.0gm LDPE Container (Plabottle) with **middle cap**	Pladexsal Injection 1000mL Each 1000mL contains: - Dextrose. . …….. … 50gm Sodium Chloride…. 9.0gm LDPE Container (Plabottle) with **euro-cap**	Initial date: 30-08-1989 Renewal applied: 13.06.2019	
6.	011225	Plabolyte-M Injection 1000mL Each 1000mL contains: - Calcium Chloride 2H2O U.S.P……..…...0.22 g Potassium Chloride U.S.P……...…1.50 g Sodium Chloride U.S.P……..…2.16 g Sodium Acetate 3H2O U.S.P……...…3.13 g Anhydrous Dextrose B.P…….. …50.0 g LDPE Container (Plabottle) with **middle cap**	Plabolyte-M Injection 1000mL Each 1000mL contains: - Calcium Chloride 2H2O U.S.P……..…...0.22 g Potassium Chloride U.S.P……...…1.50 g Sodium Chloride U.S.P……..…2.16 g Sodium Acetate 3H2O U.S.P……...…3.13 g Anhydrous Dextrose B.P…….. …50.0 g LDPE Container (Plabottle) with **euro-cap**	Initial date: 30-06-1990 Renewal applied: 14.05.2020	
7.	031126	Plabolyte-40 Injection 1000mL Each 1000mL contains: - Dextrose U.S.P…….. 50 g Potassium Chloride U.S.P……3.00 g LDPE Container (Plabottle) with **middle cap**	Plabolyte-40 Injection 1000mL Each 1000mL contains: - Dextrose U.S.P…….. 50 g Potassium Chloride U.S.P…… …3.00 g LDPE Container (Plabottle) with **euro-cap**	Initial date: 03-12-2003 Renewal w.e.f., 03.12.2018 to 02.12.2023	
8.	007782	Ringolact Injection 1000mL Each 1000mL contains: - Calcium Chloride 2H2O U.S.P……...0.20 g Potassium Chloride U.S.P……...…0.30 g Sodium Chloride U.S.P……6.00 g Sodium Lactate U.S.P……..…3.10 g LDPE Container (Plabottle) with **middle cap**	Ringolact Injection 1000mL Each 1000mL contains: - Calcium Chloride 2H2O U.S.P……...0.20 g Potassium Chloride U.S.P……..…..…0.30 g Sodium Chloride U.S.P……6.00 g Sodium Lactate U.S.P……..…3.10 g LDPE Container (Plabottle) with **euro-cap**	Initial date: 30-08-1989 Renewal applied: 28.05.2019	

9.	011224	Ringolact-D Injection 1000mL Each 1000mL contains: - Calcium Chloride 2H2O U.S.P…… 0.20 g Potassium Chloride U.S.P ……..…0.30 g Sodium Chloride U.S.P ……..…6.00 g Sodium Lactate U.S.P ……..…3.10 g Dextrose U.S.P……50 g LDPE Container (Plabottle) with **middle cap**	Ringolact-D Injection 1000mL Each 1000mL contains: - Calcium Chloride 2H2O U.S.P…… 0.20 g Potassium Chloride U.S.P ……..…..…0.30 g Sodium Chloride U.S.P ……..…..…6.00 g Sodium Lactate U.S.P ……..…..…3.10 g Dextrose U.S.P……50 g LDPE Container (Plabottle) with **euro-cap**	Initial date: 30-06-1990 Renewal applied: 21.05.2020	

The case was considered in 90th PRVC wherein the Committee decided as follows:

"The Committee decided to refer all such cases to Registration Board for consideration."

ii. Change in primary packaging to Euro-cap for already registered products applied by M/s Mediflow Pharmaceuticals (Pvt.) Ltd., Karachi.

M/s Mediflow Pharmaceuticals (Pvt.) Ltd, Karachi, applied for change in primary packaging to Euro-cap for their already registered following products:

Sr. No.	Reg. No.	Brand Name & Composition	Pack Size
1.	079596	Floviva IV Infusion Each 100ml contains: Sodium chloride_ 0.6 gm Sodium lactate_ 0.31 gm Potassium chloride_ 0.03 gm Calcium chloride.2H2O_ 0.02 gm Water for Injection qs to_ 100 mL	500ml
2.	079597	Flow DS 1/5 IV Infusion Each 100ml contains: Dextrose anhydrous_ 4.30 gm Sodium chloride…….0.18 gm Water for Injection qs to_ 100 mL-	500ml
3.	079598	Flozeal 5% Infusion Each 100ml contains: Dextrose anhydrous_ 5.0 gm Water for Injection qs to_ 100 mL	500ml
4.	079599	Floline IV Infusion Each 100ml contains: Sodium chloride_ 0.90 gm Water for Injection qs to_ 100 mL-	500ml
5.	079600	Flow DS IV Infusion Each 100ml contains: Dextrose anhydrous_ 5.0 gm Sodium chloride_ 0.90 gm Water for Injection qs to_ 100 mL-	500ml
6.	079601	Flow Dex 10% IV Infusion Each 100ml contains: Dextrose anhydrous_ 10.0 gm Water for Injection qs to_ 100 mL-	500mL
7.	079602	Flow DS ½ Infusion Each 100ml contains:	500ml

		Dextrose anhydrous_ 5.0 gm Sodium chloride_ 0.45 gm Water for Injection qs to_ 100 mL-	
8.	080617	Flow NS IV Infusion Each 100ml contains: Sodium chloride_ 0.90 gm Water for injection_ qs to 100 mL-	1000ml
9.	080618	Flow Dex 5% IV Infusion Each 100ml contains: Dextrose anhydrous_ 5 gm Water for injection_ qs to 100 mL-	1000ml
10.	080619	Flow RL IV Infusion Each 100ml contains: Sodium chloride_ 0.6 gm Sodium lactate_ 0.32 gm Potassium chloride_ 0.04 gm Calcium chloride 2H2O_ 0.027 gm Water for injection_ qs to 100 mL-	1000ml
11.		Flow Dex Each 100ml contains: Dextrose anhydrous_ 5.0 gm Water for injection_ 100 ml-	
12.	084684	Flow NS Each 100ml contains: Sodium chloride_ 0.90 gm Water for Injection qs to_ 100 mL	500ml
13.	084685	Flow NS Each 100ml contains: Sodium chloride_ 0.90 gm Water for Injection qs to_ 100 mL	1000ml
14.	084686	Flow Dex 5% IV Infusion Each 100ml contains: Dextrose anhydrous_ 5.0 gm Water for Injection qs to_ 100 mL-	500ml
15.	084687	Flow RL IV Infusion Each 100ml contains: Sodium chloride_ 0.6 gm Sodium lactate_ 0.32 gm Potassium chloride_ 0.04 gm Calcium chloride 2H2O_ 0.027 gm Water for Injection qs to_ 100 mL	500ml
16.	084688	Flow Dex 10% IV Infusion Each 100ml contains: Dextrose anhydrous_ 10.0 gm Water for Injection qs to_ 100 mL	1000ml
17.	084689	Flow DS IV Infusion Each 100ml contains: Dextrose anhydrous_ 5.0 gm Sodium chloride_ 0.90 gm Water for Injection qs to_ 100 mL	1000ml
18.	085006	Flowtol 20% IV Infusion Each 100ml contains: Mannitol_ 20 gm- Water for Injection qs to_ 100 mL	500ml

19.	085007	Flow-MTZ Infusion Each 100ml contains: Metronidazole_ 0.5 gm Water for Injection qs to_ 100 mL	100ml
20.	089079	Flow Lactate D IV Infusion Each 100ml contains: Sodium chloride_ 0.6 gm Sodium lactate_ 0.31 gm Potassium chloride_ 0.03 gm Calcium chloride 2H2O_ 0.02 gm Dextrose Monohydrate_ 5 gm Water for Injection qs to_ 100 mL	500ml
21.	089080	Flow Lactate D IV Infusion Each 100ml contains: Sodium chloride_ 0.6 gm Sodium lactate_ 0.31 gm Potassium chloride_ 0.03 gm Calcium chloride 2H2O_ 0.02 gm Dextrose Monohydrate_ 5 gm Water for Injection qs to_ 100 mL	1000ml

The firm has stated that initially they applied for Euro-cap registration in their application however, while issuance of registration letter no such details were mention in letters. The firm has requested to change their products to Euro-cap in registration letters of above products.
Submitted for consideration of Board please.

iii. Inclusion of Euro-Cap packing in registration letters of already registered products applied by M/s Frontier Dextrose Limited (FDL) , Hattar.

M/s FDL, Hattar has submitted that they had received revised MRP's approval letter from Costing & Pricing Division for their registered products in simple pack but for Euro-Cap products Costing & Pricing Division has advise them to get the variation approval letter of Euro-Cap packing from DRB. The firm further informed that Costing & Pricing Division had previously acknowledged and issued the prices for such products for many years without objection. The firm has requested for issuance of new registration letter for following Euro-Cap products without the requirement of CTD as these are already registered and marketed for many years:

Sr. No.	**Brand Name**	**Sr. No.**	**Brand Name**
1.	Mini BC 50ml	19.	Steriflutol
2.	Mini NaCl	20.	Sterilyte M
3.	Sterifluid NS	21.	Sterifluid N/3
4.	Sterifluid 5%	22.	Sterilyte
5.	Sterioflox	23.	Sterimaize 3%
6.	Sterimet	24.	Sterimaize 6%
7.	Stericipro	25.	Sterifluid 5%
8.	Sterilevo	26.	Sterifluid 10%
9.	Sterimox	27.	Sterifluid 25%
10.	Sterifluid 5%	28.	Sterifluid DS
11.	Sterifluid 10%	29.	Sterifluid NS
12.	Sterifluid DS	30.	Sterifluid RL

13.	Sterifluid NS	31.	Sterifluid RLD
14.	Sterifluid DS1/2	32.	Sterilyte M
15.	Sterifluid RL	33.	Sterifluid N/3
16.	Sterifluid RLD	34.	Sterifluid R
17.	Sterifluid R	35.	Fructosteril
18.	Sterifluid Paeds		

Decision: Registration Board advised PE&R Division to deliberate the matter with Costing & Pricing Division and to place the outcome before Registration Board.

Case No.01: Registration of Drug (s) of M/s Maxitech Pharma (Pvt.) Ltd, Plot No. E-178, S.I.T.E. Phase-II, Super Highway, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 02-12/2012-Lic dated 03-12/2018
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 07-07-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
4.	Dimed-G Plus 0.05% + 0.1% + 1% Cream Each gram contains: Betamethasone as Dipropionate.....640mcg Gentamicin as Sulphate.....1mg Clotrimazole.....10mg	Purchase order from Philippines	Dy. No. 8455 (08.08.2022) Rs.75,000/- (27.09.2022)

Decision: Registration Board approved request of the firm for registration of product for Export Purpose Only. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No.02: Registration of Drug (s) of M/s Medisure Laboratories Pakistan (Pvt.) Ltd, A-115, S.I.T.E. Super Highway Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F Nil dated 18-09-2014-Reg

GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 07-09-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	**II**	**III**	**IV**
1.	Alimin-F 50mg/20ml IV Injection Each ampoule contains: Fursultiamine.....50mg (Thiamine tetrahydrifurfuryl disulfide)	Purchase order from Myanmar. Registered in combination in PMDA Japan.	Dy. No. 8473 (17.11.2022) Rs.75,000/- (10.11.2022)

Decision: Registration Board approved request of the firm for registration of product for Export Purpose Only. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No.03: Registration of Drug (s) of M/s Saffron Pharmaceuticals (Pvt.) Ltd¸ 19-Km, Sheikhupura Road, Faisalabad, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form-5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Panel Inspection report for cGMP dated 03-01/2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 03-01-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
	Lisidipine 5mg/5mg Tablet Each tablets contains: Lisinopril (as dihydrate)…….5mg Amlodipine (as Besylate)……...5mg	Purchase order from Cambodia	Dy. No. 8506 (22.11.2022) Rs.75,000/- (03.11.2022)

Decision: Registration Board approved request of the firm for registration of product for Export Purpose Only. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No.04: Registration of Drug (s) of M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Petaro Road, Jamshoro, Pakistan for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form-5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-4/88-Lic dated 27-01/2022
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 19-05-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
	Cac Kids Effervescent Tablets (Strawberry flavor) Each effervescent tablet contains: Calcium lactate gluconate……..150mg Calcium carbonate B.P……...327mg Ascorbic acid (Vitamin C) B.P……....15mg Colecalciferol (Vitamin D3) B.P…….200IU	The firm has submitted that although the product is H&OTC product but in many other countries it is considered as drug product.	Dy. No. 8562 (01.12.2022) Rs.30,000/- (21.11.2022)

Decision: Registration Board approved request of the firm for registration of product for Export Purpose Only. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 275th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

DEFERRED CASE 320th RB

Case No.05: Registration of Drug (s) of M/s Hilton Pharma (Pvt.) Ltd, Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area, Karachi¸ for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form-5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-14/85-Lic dated 30-06/2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 19-01-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
	HIBU-P Injection 100ml Each ml contains: Ibuprofen Sodium dihydrate equivalent to Ibuprofen,.....3mg Paracetamol……10mg	Purchase order from Afghanistan	Dy. No. 7952 (04.07.2022) Rs.75,000/- (07.06.2022) 400mg/ml ibuprofen inj is available in MHRA

Decision: *Registration Board considered the case and decided as follows:*
Deferred the product at Sr No 01 for approval status of applied formulation internationally as well as in importing country.

Updated Status

The firm has firm submitted evidence of approval of formulation from TGA, Australia for above mentioned product.

Decision: Registration Board approved the request of the firm for registration of product for Export Purpose Only.

REFERRED CASE 91-PRVC

Case No.06: Registration of Drug (s) of M/s PDH Laboratories (Pvt.) Ltd, 9.5-Km, Sheikhupura Road, Lahore, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; (Pages. 179-223/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided (Page-186/C). Approval of relevant section verified from letter No. F 1-1/86-Lic dated 11-05-2022 (Page 187/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 04-01-2022 (Page 188-/C).
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided (Pages. 189-224/C)

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Alemed Injection 5mg/5ml Each 5ml ampoule contains: Midazolam.....5mg	Idazol Injection 5mg/5ml by M/s Bosch	Dy. No. 8466/22 (08.11.2022) Rs.30,000/- (25.10.2022)

Decision of 91st PRVC:

"The committee considered the case and decided to refer the product to Registration Board as Chairman is not authorized for such products being controlled drug."

Decision: Registration Board decided as follows:

i. **Approved request of the firm for registration of product for Export Purpose Only.**
ii. **Registration Board authorized its Chairman for export registration of Narcotic, Psychotropic drugs and precursor chemicals subject to availability of approved requisite manufacturing facility and NOC from Ministry of Narcotics Control.**

VETERINARY

Case No. 01:- **Request of M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore for Revision of Formulation in Accordance with Innovator/Me-too Product/Reference Regulatory Authorities and Pharmacopeias of Already Veterinary Drugs.**

M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore has requested for revision/correction of formulation in accordance with innovator/me-too product/reference regulatory authorities and pharmacopeias of already veterinary drugs. The details are as under:

S. No.	Reg. No.	Granted Composition/Salt Form.	Demanded correction Composition	Diary No.
1.	081717	Biopen 2.5gm Injection Each dry powder vial contains:- Benzyl Penicillin (USP)…...500,000IU Procaine Penicillin (USP)..1500,000IU Streptomycin Sulphate (BP)…..2.5gm	Biopen 2.5gm Injection Each dry powder vial contains:- **Penicillin G Potassium**…500,000IU **Procaine Penicillin**…….1500,000IU **Streptomycin Sulphate**……..2.5gm	Dy. No. 26285-R&I DRAP dated 16-09-2022.
2.	081718	Biopen 5gm Injection Each dry powder vial contains:- Benzyl Penicillin (USP)…...500,000IU Procaine Penicillin (USP)..1500,000IU Streptomycin Sulphate (BP)……..5gm	Biopen 5gm Injection Each dry powder vial contains:- **Penicillin G Potassium**…500,000IU **Procaine Penicillin**…….1500,000IU **Streptomycin Sulphate**…….5gm	

M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore has deposited the required fee of **Rs.30,000 x 2 = Rs.60,000/-** and submitted following supporting documents:-

(i) Copy of initial registration letter.
(ii) Last renewal trails.
(iii) Supporting documents for change of composition.
(iv) Undertaking that the provided information/documents are true/correct.

Benzylpenicillin, also known as penicillin G. (https://pubchem.ncbi.nlm.nih.gov/compound/Penicillin-g).
As per USP **Penicillin G** complete salt form is "**Penicillin G Potassium"** and same is applied by the firm for revision of Benzyl Penicillin presentation.

Decision:- **Registration Board considered and approved the revision of formulation in accordance with innovator/me-too product/reference regulatory authorities and pharmacopeia as per following details:**

S. No.	Reg. No.	Granted Composition/Salt Form.	New Approved Composition
1.	081717	Biopen 2.5gm Injection Each dry powder vial contains:- Benzyl Penicillin (USP)…...500,000IU Procaine Penicillin (USP)..1500,000IU Streptomycin Sulphate (BP)…..2.5gm	Biopen 2.5gm Injection Each dry powder vial contains:- **Penicillin G Potassium**…500,000IU **Procaine Penicillin**…….1500,000IU

			Streptomycin Sulphate……..2.5gm
2.	081718	Biopen 5gm Injection Each dry powder vial contains:- Benzyl Penicillin (USP)…...500,000IU Procaine Penicillin (USP)..1500,000IU Streptomycin Sulphate (BP)……..5gm	Biopen 5gm Injection Each dry powder vial contains:- **Penicillin G Potassium**…500,000IU **Procaine Penicillin**…….1500,000IU **Streptomycin Sulphate**…….5gm

Case No. 02:- Registration of Drugs under the Drugs Act, 1976.

Following non-drug diluents are registered in different meeting of Registration Board and processed.

S. No.	Reg. No.	Manufacturer	Name of Drug(s) & Composition.
1.	111532	M/s. ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.	ISIS Diluent (for eye drops vaccines) Each ml contains:- Monobasic Potassium Phosphate……0.37mg Disodium Phosphate Dihydrate……0.72mg Sodium Chloride……..…7.65mg (As per Innovator's Specification)*
2.	112108	M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura.	Diluent VAC Each ml contains:- Monobasic Potassium Phosphate…….....0.37mg Disodium Phosphate Dihydrate…….....0.72mg Sodium Chloride……..7.65 mg Disodium Edetate Dihydrate…….…….0.50mg (As per Innovator's Specification)*

Registration Board approved API of drug products only.

Registration Board in its 320th meeting deferred the case for further deliberation.

Decision:- Registration Board deliberated that applied formulations are diluents (non-drug formulations) for administration / re-constitution of registered vaccines and registrations are granted for drug products only. The Board advised to review practices of various regulatory authorities (reference/non-reference) and also seek opinion of Legal Affair division regarding either grant of registration or permission to manufacture in a licensed facility.

Case No.03:- Request of M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore for Standardization of Formulation in Accordance with the Innovator's Product/Reference Regulatory Authorities and Pharmacopeia.

M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore has requested for standardization of formulation with the innovator's product/reference regulatory authorities and pharmacopeia of their following registered drug as per detail mentioned against each:-

S. No.	Regn. No.	Product Granted Composition	Demanded Composition	Remarks/ Diary No. R&I & Initial date of Regn.

I	II	III	IV	V
1.	111307	Cynosel Forte 1000mcg Injection **Each 2ml contains:-** Cyanocobalamin …1000mcg	Cynosel Forte 1000mcg Injection **Each ml contains:-** Cyanocobalamin …1000mcg	Dy. No. 4273-R&I DRAP dated 14-02-2022. 04th January, 2022

M/s. Selmore Pharmaceuticals (Pvt) Ltd., Lahore has deposited the required fee of Rs.30,000/- and submitted following supporting documents:-

(i) Copy of Registration letter.
(ii) Copy of me-too reference.
(iii) Undertaking.

Demanded composition already registered various firms including M/s. Baariq Pharmaceuticals, Lahore & M/s. Wimits Pharmaceuticals, Lahore vide registration No.097872 & 102042 respectively.

Remarks:

Approved composition and demanded composition of M/s Selmore is available in generic/me-too separately.

The case was discussed in its 79th Post Registration Variation Committee (PRVC) and the committee evaluated the case and Chairman Registration Board, on the recommendations of the committee, decided to not accede the firm request as demanded composition is new drug formulation.

Remarks:- Initially case was discussed in 312th meeting of Registration Board for two volume 50ml & 100ml with label claim each 2ml contain Cyanocobalamin 1000mcg. 50ml approved and letter issued dated 04-01-2022, while 100ml approved in 316th meeting with label claim correction i.e. each ml contains Cyanocobalamin…..1000mcg with full fee. Now firm request for correction of label claim of 50ml accordingly.

The case was discussed in its 89th meeting of Post Registration Variation Committee (PRVC) and the committee evaluated the case and Chairman Registration Board, on the recommendations of the committee, decided to refer to Registration Board.

Decision:- Registration Board considered and approved the standardization of formulation in accordance with the already registered product as per following details:

S. No.	Regn. No.	Product Granted Composition	New Approved Composition
1.	111307	Cynosel Forte 1000mcg Injection **Each 2ml contains:-** Cyanocobalamin …1000mcg	Cynosel Forte 1000mcg Injection 50ml **Each ml contains:-** Cyanocobalamin …1000mcg

Case No. 04 :- Request of M/s. Onesto Enterprises (Private) Limited, Islamabad for Transfer of Registration of Already Registered Imported Veterinary Drugs.

M/s. Onesto Enterprises (Pvt) Ltd, Flat No.304, Third Floor, Civic Centre, Phase-4, Bahria Town, Islamabad request for transfer of registration of their already registered imported veterinary drugs from the name of previous importer M/s. Bayer Pakistan (Pvt) Ltd, C-21, S.I.T.E, Karachi to their name. The details are as under:-

S.	Regn. No.	Name of Drug (s)/ Composition as per initial registration letters.	Manufacturer as per initial registration letter	Manufacturer/ Product License Holder as per CoPP	Approved pack size as per	Initial date of registration/

					initial registration letter/ shelf life as initial registration letter	**renewal status**
1.	039969	Catosol 10% Injectable Solution Each 100ml contains:- Butaphosphane (rec.INN)……10gm Vitamin B12…….....5 mg	M/s. Bayer AG, HealthCare, Germany.	**As per Form-5A** Assembler M/s. KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24 1106 Kiel Germany **As per CoPP** **Product License Holder:** M/s. Elanco GmbH Heinz-Lohmann-str. 4 27472 cuxhaven Germany **Manufacturer Assembler** M/s. KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24106 Kiel Germany **Bulk Manufacturer:** M/s. Elanco US Inc. Shawnee Mission Parkway, 12707 66216 Shawnee, Kansas United States.	100ml Shelf life not mentioned in registration letter Shelf life 5 years as Form-5A	01-04-2016 Pre-registration for change of address on 02nd June, 2011
2.	029688	Rompun 2% Injectable Solution Each ml contains:- 23,32mg of 2-(2.6-xylidino)-5.6-dihydro-4H-1.3-thiazine-hydrochloride	M/s. Bayer AG, Germany.	**As per Form-5A** Assembler KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24 1106 Kiel Germany **As per CoPP**	100ml 1000ml not mentioned in registrati	19-07-2003 24-08-2015

		(equivalent to 20mg active ingredient) Methylparaben……. 1mg		**Product License Holder:** M/s Elanco GmbH Heinz-Lohmann-str. 4 27472 cuxhaven Germany **Manufacturer Assembler** KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24106 Kiel Germany **Bulk Manufacturer:** Elanco US Inc. Shawnee Mission Parkway, 12707 66216 Shawnee, Kansas United States	on letter Shelf life 3 years as For m-5A	
3.	029689	Baycox 2.5% Oral Solution Each ml contains:- Toltrazuril……25. 0mg	M/s. Bayer AG, Germany.	**As per CoPP & Form-5A** **Product License Holder:** M/s. Elanco GmbH Heinz-Lohmann-str. 4 27472 cuxhaven Germany **Manufacturer:** M/s. KVP Pharma + Veterinary Produkte GmbH Projensdorfer Strabe 324 24106 Kiel Germany.	100ml 1000ml not mentioned in registration letter Shelf life 5 years as For m-5A	19-07-2003 24-08-2015

M/s. Onesto Enterprises (Pvt) Ltd, Flat No.304, Third Floor, Civic Centre, Phase-4, Bahria Town, Islamabad has deposited required fee of Rs.150,000 x 3 = Rs. 450,000/- and submitted the following documents:-

i) Photocopy of No Objection Certificates from M/s. Bayer Pakistan (Pvt) Ltd, C-21, S.I.T.E, Karachi issued on 19-05-2022.
ii) Original legalized CoPP
iii) Original & Legalized GMP Compliance issued by State Social Services Agency Schleswing-Holstein, Germany.
iv) Explanation letter.
v) Letter of Authorization.
vi) Termination of Authorization.
vii) Copy of Drug Sale License valid upto 27-11-2022.
viii) Undertaking.
ix) Site Master File along with Form-5A of above-mentioned drugs.

Decision:- **Registration Board decided as follow;**

(a) Cancellation of registration products from the name of M/s. Bayer Pakistan (Pvt) Ltd, C-21, S.I.T.E, Karachi.

(b) Approved the registration of above mentioned products of above table in the name of M/s. Onesto Enterprises (Pvt) Ltd, Flat No.304, Third Floor, Civic Centre, Phase-4, Bahria Town, Islamabad as per finished import policy. The details are as under:-

S. No.	Regn. No.	Name of Drug (s)/ Composition as per initial registration letters.	New approved Manufacturer & Product License Holder.	Shelf Life	Approved pack size as per initial registration letter
1.	039969	Catosol 10% Injectable Solution Each 100ml contains:- Butaphosphane (rec.INN)…10gm Vitamin B12……...5mg	**As per Form-5A** Assembler M/s. KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24 1106 Kiel Germany **As per CoPP** **Product License Holder:** M/s. Elanco GmbH Heinz-Lohmann-str. 4 27472 cuxhaven Germany **Manufacturer** **Assembler** M/s. KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24106 Kiel Germany **Bulk Manufacturer:** M/s. Elanco US Inc. Shawnee Mission Parkway, 12707 66216 Shawnee, Kansas United States.	5 years	100ml
	029688	Rompun 2% Injectable Solution Each ml contains:- 23,32mg of 2-(2.6-xylidino)-5.6-dihydro-4H-1.3-thiazine-hydrochloride (equivalent to 20mg active ingredient) Methylparaben……..1mg	**As per Form-5A** Assembler KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24 1106 Kiel Germany **As per CoPP** **Product License Holder:** M/s Elanco GmbH Heinz-Lohmann-str. 4 27472 cuxhaven Germany **Manufacturer** **Assembler** KVP Pharma + veterinary Produkte GmbH Projensdorfer Strabe 324 24106 Kiel Germany	3 years	100ml 1000ml

			Bulk Manufacturer: Elanco US Inc. Shawnee Mission Parkway, 12707 66216 Shawnee, Kansas United States		
	029689	Baycox 2.5% Oral Solution Each ml contains:- Toltrazuril……25.0mg	**As per CoPP & Form-5A** **Product License Holder:** M/s. Elanco GmbH Heinz-Lohmann-str. 4 27472 cuxhaven Germany **Manufacturer:** M/s. KVP Pharma + Veterinary Produkte GmbH Projensdorfer Strabe 324 24106 Kiel Germany.	5 years	100ml 1000ml

Case No.05:- Requirement for steroidal manufacturing facility.

Registration Board in its 308th meeting deferred products for discussion regarding requirement for steroidal manufacturing facility of M/s. Vetz Pharmaceuticals (Pvt) Ltd., Kotri, Sindh of below mentioned drugs. The details are as under:-

1.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Progevet Injection (10ml)
	Composition	Each ml contains:- Progestrone (USP)……..25mg
	Diary No. Date of R& I & fee	Dy.No 14577 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	10ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Pregtone Injection of M/s. Star Labs. (Reg.#058711)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	**steroidal manufacturing facility?**
2.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Progevet Injection (50ml)
	Composition	Each ml contains:- Progestrone (USP)……..25mg
	Diary No. Date of R& I & fee	Dy.No 14578 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Harmones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	50ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A

	Me-too status (with strength and dosage form)	Progestone Injection of M/s. Symans Pharmaceuticals (Pvt) Ltd., Lahore Registration No 063695
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	**steroidal manufacturing facility?**
3.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Cyclovet Injection (2ml)
	Composition	Each ml contains:- Cloprostenol Sodium 263mcg (B.P Vet) equivalent to Cloprostenol…….250mcg
	Diary No. Date of R& I & fee	Dy.No 14573 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Harmones
	Type of Form	Form-5
	Finished product Specifications	BP -Vet Specification
	Pack size & Demanded Price	2ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Cyclomate Injection (2.0 ml) M/s. Star Labs. Reg.No 012877
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
4.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Cyclovet Injection (10ml)
	Composition	Each ml contains:- Cloprostenol Sodium 263mcg (B.P Vet) (equivalent to cloprostenol)…….250mcg
	Diary No. Date of R& I & fee	Dy.No 14574 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Harmones
	Type of Form	Form-5
	Finished product Specifications	BP -Vet Specification
	Pack size & Demanded Price	10ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Prostenol Injection (10.0ml) M/s. Selmore Labs. R.No. 029611
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	
5.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Lecivet Injection (2ml)
	Composition	Each ml contains:- Lecirelin (MS)…25mcg
	Diary No. Date of R& I & fee	Dy.No 14571 dated 28-05-2021 PKR 30,000/- : 25-05-2021

	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	In house Specification
	Pack size & Demanded Price	2ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Serilin Injection (2.0, 10.0ml) M/s. Selmore Laboratories Registration No 071092
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	**7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 is required.**
6.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Lecivet Injection (10ml)
	Composition	Each ml contains:- Lecirelin (MS)……..25mcg
	Diary No. Date of R& I & fee	Dy.No 14572 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	In house Specification
	Pack size & Demanded Price	10ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Serilin Injection (2.0,10.0ml) M/s. Selmore Laboratories Registration No. 071092
	GMP status	The firm was inspected on 31-5-2021with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator	**7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 is required.**
7.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceutical (Pvt) Ltd Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form+ Strength	Dinopovet Injection (5ml)
	Composition	Each ml contains:- Dinoprost (as trometamol) (EP)…….5mg
	Diary No. Date of R& I & fee	Dy.No 14570 dated 28-05-2021 PKR 30,000/- : 25-05-2021
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	5ml/Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Dprost Injection (5.0ml) M/s. Selmore Laboratories Registration No 088647
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.

	Remarks of the Evaluator	

(i) We are going to submit comprehensive reply on our 6 products namely (i) Progevet Injection 10ml (ii) Progevet Injection 20ml (iii) Cylovet Injection 2ml (iv) Cylovet Injection 10ml (v) Lecivet Injection 2ml (vi) Lecivet Injection 10ml & Dinopevet Injection 5ml. We desire the manufacturing facility for hormones.

(ii) Here we desire the condition in which production dedicated area clearly mentioned to hormone according to Schedule-B Drug Licensing and Registering and Advertising Rule in 1976. Keeping in this view we prepared separate and dedicated area's for hormone section. We apply 14 products for registration, so we request the Registration Board that all applied products in hormone section should be granted, if all products are being registered so the products containing oxytocin hormone should be suspended till we prepare new area and rest deferred products should be allotted because only two products does not meet expense of the area. We hope that above narrator will satisfy you.

The details of already registered hormone products are as under:-

S. No.	Reg. No.	Name of Drug(s) & Composition.	Packing	Maximum Retail Price.	Approved Shelf Life.
1.	109960	Buserovet Injection Each ml contains:- Buserelin Acetae…….0.0042mg equivalent to Buserelin…..0.004mg (As per Innovator's Specification)*	2.5ml	De-controlled	02 years
2.	109961	Buserovet Injection Each ml contains:- Buserelin Acetae..…...….0.0042mg (equivalent to Buserelin.....0.004mg (As per Innovator's Specification)*	5ml	De-controlled	02 years
3.	111468	Oxytovetz Injection Each ml contains:- Oxytocin (USP)……..10 IU (USP Specifications)	50ml	De-controlled	02 years
4.	111469	Oxytovetz Injection Each ml contains:- Oxytocin (USP)…..….10 IU (USP Specifications)	100ml	De-controlled	02 years
5.	111470	Oxytovetz Injection Each ml contains: Oxytocin (USP)……..10 IU (USP Specifications)	250ml	De-controlled	02 years
6.	111471	Oxytovetz Injection Each ml contains:- Oxytocin (USP)……..10 IU (USP Specifications)	500ml	De-controlled	02 years
7.	111472	Oxytovetz Injection Each ml contains:- Oxytocin (USP)……20 IU (USP Specifications)	100ml	De-controlled	02 years

Decision M-321: Registration Board considered and deferred for further deliberation M/s Vetz pharma submitted that they intend to manufacture only hormonal products in the said facility and accordingly products registration letter may be issued.

Decision: Registration Board deliberated the matter and decided as follows:

a. **Approved products from S.No. 3-7.**
b. **Deferred products from S.No.1-2 for steroidal manufacturing facility.**

Case No.06: Deferred cases (M-321) Locally Manufactured Veterinary Drugs.

1.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Prokill Powder
	Composition	Alkyl (60% C_{14}, 30% C_{16}, 5%C_{12}, 5%C_{18}) dimethyl benzyl ammonium chloride… 40%. Inert Ingredient: urea……...60%
	Diary No. Date of R& I & fee	Rs.30,000/- (21009/26.07.2022)
	Pharmacological Group	External Powder Preparation (Disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	250g , 500g , 1Kg , 5Kg / Decontrolled
	Me-too status	TIMSEN Powder Registration No: 043101 by M/s GHAZI BROTHERS, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Me-too not same as applied product
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The firm has revised the formulation according to reference product as: Alkyl (60% C14, 30% C16, 5%C12, 5%C18) dimethyl Benzyl ammonium chloride… 40% and deposited the Fee of Rs. 30000/- vide bank deposited Slip No. **5747962544** dated **16.09.2022** **Decision:- Deferred for clarification regarding intended use / indication of applied formulation.**	
2.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	PSEL (Sterile Water For Injection) 80ml
	Composition	Each vial contains:- Sterile Water for Injection (as diluent) … 80ml
	Diary No. Date of R& I & fee	Rs.30,000/- (20983/26.07.2022)
	Pharmacological Group	Diluent/Solvent for Reconstitution
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	80ml / Decontrolled
	Me-too status	PSOL (Sterile Water for Injection) Registration No: 090136. by M/s Pharmasol Pvt Ltd Lahore, Pakistan.

	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Submitted me-too of Human drug You have mentioned B.P and USP in specification, mention desired one
	Decision: Deferred for details of the drug product for which applied formulation will be used as diluent. The firm has stated that the PSEL (sterile water for injection) as diluent will be used for **Ceftisel Each Dry Powder 4gm** Each vial contains : Ceftiofur Sodium equivalent to Ceftiofur ……..4g Approved in 321st DRB Meeting. **Decision:- Approved**	
3.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Septisel 10% Solution
	Composition	Each Litre contains:- Di-decyl-di-methyl-ammonium bromide….10%
	Diary No. Date of R& I & fee	Rs.30,000/- (21004/26.07.2022)
	Pharmacological Group	External Liquid Preparation (disinfectant)
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	1 Litre, 2.5 Litre, 5 Litre / Decontrolled
	Me-too status	BROMO-SEPT Solution. Registration No: 017054, by M/s SELMORE AGENCIES, Lahore.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Generic is not same as applied.
	Decision: Deferred for clarification regarding intended use / indication of applied formulation.	
4.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cefagent-AD LC Intramammary Suspension.
	Composition	Each 10ml contains:- Cephalexin Monohydrate (Base)…..200mg Gentamicin Sulphate (Base)…....100mg Dexamethasone-21 phosphate……..0.75mg Vitamin A……..10,000 IU
	Diary No. Date of R& I & fee	Rs.30,000/- (20991/26.07.2022)
	Pharmacological Group	Antibiotic-Anti-inflammatory combination
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	48 Injectors of 10ml / Decontrolled
	Me-too status	CEFA MILK FORTE Intramammary Suspension Registration No: 053955, by M/s Mustafa Brothers Faisalabad
	GMP status	New Section Approval granted on 04-07-2022

	Remarks of the Evaluator.	Cephalexin and Gentamicin salt form presentation is not as per reference
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syrine filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
5.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Uteprim Intrauterine Suspension
	Composition	Each 19gm syringe contains:- Cephapirin as benzathine……..500mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20992/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specs.
	Pack size & Demanded Price	10 Injectors of 19 gm / Decontrolled
	Me-too status	METRICURE Intrauterine Suspension Registration No: 078355.by ICI Pakistan, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syrine filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
6.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cepramast DC Intramammary Suspension
	Composition	Each 3gm syringe contains:- Cefalonium…….250mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20994/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	(BP-vet Specs.)
	Pack size & Demanded Price	24 Injector of 3mg / Decontrolled
	Me-too status	CEPRAVIN Intramammary Suspension Registration No: 020133 by ICI Pakistan, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	Reference presentation: Cefalonium 250 mg (as cefalonium dihydrate)
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area.	

	Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.	
7.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Redycef LC Intramammary Suspension
	Composition	Each 10ml syringe contains: Ceftiofur as Hydrochloride…… 125mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20995/26.07.2022)
	Pharmacological Group	Broad-spectrum Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	12 Injectors of 10ml / Decontrolled
	Me-too status	SPECTRA MAST LC Intramammary Suspension Registration No: 088652.by M/s GHAZI BROTHERS, Karachi
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
8.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Redycef DC Intramammary Suspension
	Composition	Each 8ml syringe contains: Ceftiofur as Hydrochloride……500mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20996/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	5 Injectors of 8ml / Decontrolled
	Me-too status	CEFENT DC Intramammary Suspension Registration No: 093830. by M/s UM Enterprises, Karachi.
	GMP status	New Section Approval granted on 04-07-2022
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	

9.	Name and address of manufacturer / Applicant	**M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Redycef RTU Injection 10ml.
	Composition	Each ml contains: Ceftiofur as hydrochloride…… 50mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20986/26.07.2022)
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	10ml / Decontrolled
	Me-too status	CEFUR-RTU Injection, Registration No: 049605 by M/s. Nawan Laboratories Pvt. Ltd. Karachi, Pakistan
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator	Me-too granted 50,100ml
	. Firm submitted generic status i.e CEFUR-RTU (Reg. 049605) of M/s Nawan Laboratories Karachi **Decision:- Approved with innovator's specifications.**	
10.	Name and address of manufacturer / Applicant	M/s. Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cefagent LC Intramammary Suspension
	Composition	Each 10ml syringe contains:- Cefalexin as Monohydrate……..350mg Gentamicin as Sulphate……35mg
	Diary No. Date of R& I & fee	Rs.30,000/- (20993/26.07.2022)
	Pharmacological Group	Antibiotic Combination.
	Type of Form	Form-5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	24 Injectors Of 10ml / Decontrolled
	Me-too status	MASTILEX Intramammary Suspension Registration No: 019980. by M/s VETARIA Pharmaceuticals, Lahore
	GMP status	New Section Approval granted on 04-07-2022
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of availability of manufacturing facility for Intra mammary injections. The firm has provided detail of Syringe filling machine capacity 1-80ml Eq. No. SED-1BYGF-K in list of Cephalosporin liquid Injectable area. **Decision:- Registration Board refer the case to Licensing Division for confirmation of manufacturing facility for Intra mammary injections.**	
Oral Liquid (General) Section (Veterinary) 11 Molecules/12 Products		
11.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals (Pvt) Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Med TS Oral Liquid
	Composition	Each 1000ml contains:-

		Enrofloxacin…….75gm Sulphamethoxypyridazine…75gm Sulphamerazine ……..50gm Trimethoprim……...25gm
	Diary No. Date of R& I & fee	Dy No:10033, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml/ Decontrolled
	Me-too status (with strength and dosage form)	Cina T.S Oral Suspension by M/s Vety-Care Pharmaceutical (Pvt) Ltd (Reg#031456)
	Remarks of the Evaluator	Me-too is not same
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm submitted generic status Cina T.S Oral Suspension by M/s Vety-Care Pharmaceutical (Pvt) Ltd (Reg#031456) **Decision: Registration Board refer the case to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.**	
	Oral Dry Powder (General) Section (Veterinary) 10 Molecules/10 Products	
12.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Med Erythro Plus Oral Powder
	Composition	Each 1000gm Contains: Tylosin Tartrate…….60gm Erythromycin Thiocyanate……40gm Bromhexine HCl……..5gm
	Diary No. Date of R& I & fee	Dy No:10040, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & mucolytic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Tylovit E.F Plus Powder by M/s Leads Pharma (Pvt) Ltd (Reg#044963) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Generic submitted by the firm:** Tylovit e.f plus powder Each kg contains:- Tylosin tartrate ……..….60gm Furaltodone HCL ……..…150gm Bromhexine HCL……..…..05gm Erythromycin thiocyanate…….40gm	

	Decision:- Registration Board deferred the case containing salt Furaltodone. Show cause already issued to other firm containing salt Furaltodone.	
13.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan
	Brand Name +Dosage Form + Strength	Paradox Oral Powder
	Composition	Each 1000gm contains:- Doxycycline HCl……..200gm Tylosin Tartrate……100gm Colistin Sulphate……...500 MIU Aminophylline HCl…..…100gm Paracetamol……..100gm
	Diary No. Date of R& I & fee	Dy No:10047, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic, mucolytic & antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	**Not submitted**
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: **Decision:- Registration Board refer the case to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters**	
14.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Fosfomox Oral Powder
	Composition	Each 1000gm contains:- Calcium Fosfomycin……..200gm Tylosin Tartrate……..100gm Fructose……..180gm Sodium Phosphate……..150gm Magnesium Phosphate……100gm
	Diary No. Date of R& I & fee	Dy No:10044, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & minerals
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1000gm/ Decontrolled
	Me-too status (with strength and dosage form)	Fofact Powder by M/s Univet Pharmaceuticals (Reg#075626) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Firm submit generic status FOSBIOTIC 20 ORAL POWDER (Reg.# 106752) of M/s Grand Pharma Islamabad **Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for**	

	revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
	Oral Dry Powder (Penicillin) Section (Veterinary) 7 Molecules/ 8 Products	
15.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Splino Mox Oral Powder
	Composition	Each 1000gm contains:- Amoxicillin Trihydrate……....200gm Lincomycin HCl……....88gm Spectinomycin 2HCL…….88gm
	Diary No. Date of R& I & fee	Dy No:10022, Dated:20-04-2022, Rs. 30,000, Dated:18-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Me-too status (with strength and dosage form)	Harry-Speclin 200 Water Soluble Powder by M/s Haarolds Pharmaceuticals (Pvt) Ltd (Reg#109164) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Firm submit generic status SPECTOMOX FORTE ORAL POWDER (Reg.#102078) of M/s Grand Pharma Islamabad **Decision: Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
16.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Medlimox B Oral Powder
	Composition	Each 1000gm contains:- Amoxicillin Trihydrate……100gm Lincomycin HCl…….50gm Colistin Sulphate…….26.3gm Bromhexine HCl……5gm
	Diary No. Date of R& I & fee	Dy No:10048, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic & mucolytic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg/ Decontrolled
	Me-too status (with strength and dosage form)	Tycobar-D Water Soluble Powder by M/s Baariq Pharmaceuticals (Reg#071099) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.

	Firm has submitted a revised formulation with generic status AMCOLINX WATER SOLUBLE POWDER (Reg. 102075) of M/s Grand Pharma Islamabad Each 100gm contains:- Amoxicillin Trihydrate…….…….……10gm Lincomycin HCl…….…….5gm Colistin Sulphate…….…….……...50MIU Bromhexine HCl……..……0.5gm **Decision:- Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of 30,000/- fee for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 with following composition:-** Each 100gm contains:- Amoxicillin as Trihydrate…….…….……10gm Lincomycin HCl…….…….…5gm Colistin Sulphate…….…….……...50MIU Bromhexine HCl……..……0.5gm	
17.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Pro Medcin Oral Powder
	Composition	Each 1000gm contains:- Streptomycin Sulphate…….…….36gm Procaine Penicillin…….…….……12gm Zinc Bacitracin……..……..52gm Sodium Selenite……0.5mg
	Diary No. Date of R& I & fee	Dy No:10045, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1kg, 5kg, 25kg/ Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Procabact Powder by M/s Grand Pharma (Pvt) Ltd (Reg#106630) (Not same as applied formulation)
	GMP status	05-11-2021 Panel inspection for grant of DML Panel recommended grant of DML.
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Firm has submitted a revised formulation with generic status SPECTOMOX SUPER WATER SOLUBLE POWDER (Reg.102079) of M/s Grand Pharma Islamabad Each 100gm contains:- Amoxicillin Trihydrate ……..……20gm Lincomycin HCl…….……...…9gm Spectinomycin Dihydrochloride……..8.8gm	

	Decision:- Approved with innovator's specifications. Registration Board further decided that registration letter will be issued after submission of 30,000/- fee for revision of formulations as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 with following composition:- Each 100gm contains:- Amoxicillin as Trihydrate ……..…20gm Lincomycin HCL…….....…9gm Spectinomycin Dihydrochloride……...8.8gm	
18.	Name and address of manufacturer / Applicant	M/s. Medhouse Pharmaceuticals Pvt Ltd. Mouza Mangowal Gharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat, Punjab, Pakistan.
	Brand Name +Dosage Form + Strength	Med Exel Oral Powder
	Composition	Each 1000gm contains:- Neomycin Sulphate…….10gm Streptomycin Sulphate……36gm Procaine Penicillin……..12gm Zinc Bacitracin……52gm Colistin Sulphate……500,000 IU
	Diary No. Date of R& I & fee	Dy No:10043, Dated:20-04-2022, Rs. 30,000, Dated: 29-03-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	20gm, 100gm, 500gm, 1Kg, 5Kg, 25Kg/ Decontrolled
	Me-too status (with strength and dosage form)	Flemibiotic Powder by M/s Grand Pharma (Pvt) Ltd (Reg#103942) (Not same as applied formulation)
	Remarks of the Evaluator	• Me-too status not confirmed from available me-too database.
	Decision: Registration Board refer the case to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	

M/s Evergreen Pharmaceuticals.
69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
DML No. 000786 (Formulation)
Central Licensing Board in its 287th meeting held on 24th June, 2022 has considered and approved the grant of following sections in the name of M/s Evergreen Pharmaceuticals, vide approval letter No. F. 1-31/2010- Lic (Vol-1) dated 4th July, 2022: -

Oral powder penicillin section
7 Molecule/10 Products

19.	Name and address of manufacturer / Applicant	M/s. Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Mycomox Powder
	Composition	Each 1000gm contains:- Amoxicillin Trihydrate eq. to Amoxicillin.…100gm Colistin Sulphate…….…..…500 MIU Neomycin Sulphate…….200gm

	Diary No. Date of R& I & fee	Dy. No 5216: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Amcocin (Reg. 083243)
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm shall be submitted
	Decision M-321: **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **Remarks:** **Firm request to process as per generic.** Each 1000gm contains:- Amoxicillin Trihydrate Eq. to Amoxicillin.…100gm Colistin Sulphate…….……50 MIU Neomycin Sulphate……..200gm **Decision: Approved with innovator's specifications and with following label claim:** Each 1000gm contains:- Amoxicillin as Trihydrate ……..100gm Colistin Sulphate…….……50 MIU Neomycin Sulphate……..200gm **Registration Board further decided that registration letter will be issued after submission of 30,000/- fee for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
20.	Name and address of manufacturer / Applicant	M/s. Evergreen Pharmaceuticals. 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Moxicol Water Soluble Powder
	Composition	Each 1000gm contains:- Amoxicillin Trihydrate……..…200gm Colistin Sulphate……...800 IU
	Diary No. Date of R& I & fee	Dy. No 5215: 24-02-2022 PKR 30,000/-: 21-02-2022
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator specification
	Pack size & Demanded Price	500gm, 1000gm: Decontrolled
	Me-too status	Moxabect w/s Powder (Reg#088642)
	Remarks of the Evaluator	Amoxicillin molecule presentation is not as per reference
	Decision M-321: **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **Remarks:** **Firm request to process as per generic.** Each 1000gm Contains: Amoxicillin Trihydrate……..200gm Colistin Sulphate…….800MIU **Decision: Approved with innovator's specifications and with following label claim:**	

	Each 1000gm contains:- Amoxicillin as Trihydrate……..200gm Colistin Sulphate……..800MIU **Registration Board further decided that registration letter will be issued after submission of 30,000/- fee for revision of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

Import & Vet-II Section

Case No.01. REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR CHANGE OF MANUFACTURING SITE FOR THEIR REGISTERED PRODUCTS.

The subject case was discussed and defer in 79th PRVC & 80th PRVC as under: -

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has applied for change of manufacturing site for their following already registered products as per details given below: -

Sr. #	Name & Composition	Existing approved Site (as per approval)	New Proposed Site / Manufacturer/ Product License Holder (as per COPP)
1.	Sandostatin 0.05mg/ml ampoule Each ml ampoule contains: Octreotide….0.05mg Reg. No.013473	M/s Sandoz Pharma Ltd Basle, Switzerland	**Product License Holder: -** M/s. Novartis pharma schweiz AG, 6343, risch, Switzerland **Manufacturer: -** M/s Delpharm Dijon 6 boulevard de l'Europe 21800 Quetigny France.
2.	Sandostatin 0.1mg/ml ampoule Each ml ampoule contains: Octreotide….0.1mg Reg. No.013472	M/s Sandoz Pharma Ltd Basle, Switzerland	

The firm has submitted the following supporting documents: -

Change of Address of Manufacturing Site/Source/Marketing Authorization Holder (MAH).	
Documents required as per SOPs	**Submitted documents by firm**
a) Application with required fee as per relevant SRO. b) Copy of registration letter and last renewal status. c) Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin. d) Site master file of new manufacturing site in case of change of manufacturing site/ source.	a) Application on form 5F along with Fee of Rs.75,000/- for each product dated 18-11-2021 & Rs.75,000/- dated 03-03-2022 for each product. b) Copy of registration letter of Sandostatin 0.05mg/ml & 0.1mg/ml ampoule Issued on 19-01-1993 Approval for change of name to M/s Novartis Pharma (Pakistan) Ltd, Karachi with transfer of Registration on 23-06-2007 Renewal due date 22-06-2017 Renewal submit on 30-03-2017 c) Original & legalized CoPP issued by Swissmedic.

e) Revised Sole Agency Agreement when there is change in MAH. f) Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities. g) Undertaking that the provided information/ documents are true/ correct.	d) Site master file submitted e) No change in MAH f) Sole agency agreement and relationship between MAH & Manufacturer. g) Provided

Decision 79th PRVC

On the recommendations of the committee, Chairman Registration Board considered and defer the case as submitted data of product is not of new manufacturing site.

Reply of the firm.

The firm has submitted their reply.

Product Name	Your Query	Our Response
Sandostatin 0.05 mg/ml Ampoule (Reg. No. 013473) AND **Sandostatin 0.1** mg/ml Ampoule (Reg. No. 013472)	1. Submitted data of product is not new manufacturing site. 2. Sandostatin 0.05mg/ml ampoule and Sandostatin 0.1mg/ml ampoule manufacturer as per initial registration letter and your application is not same, Clarify	1. We are submitting the following documents, showing our application is for new manufacturing site change: (i) Manufacturer's name on CTD (ii) Already submitted CPP (iii) Already submitted LoA 2. Please note that Sandoz and Ciba-Geigy was merged in 1996. We informed to ex-Ministry of Health regarding merger and submitted all relevant documents for change of title from Sandoz/Ciba-Geigy to Novartis. In this application, we submitted change of manufacturing site from Novartis Basel to Novartis Stein as a package and we obtained approval for change of title. We are enclosing these documents for your kind consideration.
Sandostatin 0.5 mg/ml Ampoule (Reg. No. 086485)	Submitted data of product is not new manufacturing site.	3. We are submitting again the following documents, showing our application for new manufacturing site change: (i) Manufacturer's name on CTD (ii) Already submitted CPP (iii) Already submitted LoA

Remarks: Initial registration letter shows that M/s Sandoz Pharma Ltd Basle, Switzerland is manufacturer but firm submitted covering letter shows that M/s. Novartis pharma stein ag, schaffhauserstrasse, 4332 stein, Switzerland is previous manufacturer.

Firm inform to ministry dated 25th April 1997 as per their application their name of parent company changed from M/s Sandoz Pharma AG Basle, Switzerland to M/s Novartis Pharma AG Basle, Switzerland. M/s Novartis Pakistan have no approval of this.

Form-5F shows manufacturer of finished product is M/s. Novartis pharma stein ag, schaffhauserstrasse, 4332 stein, Switzerland.

Decision of 80th PRVC:

On the recommendations of the committee, Chairman Registration Board considered and deferred the case for followings:

i. Cclarification regarding import of these products the name of M/s Novartis Pharma AG Basle, Switzerland while as per available record M/s Sandoz Pharma Ltd Basle, Switzerland is the manufacturer.
ii. Moreover, submitted data regarding form-5F is of old manufacturing site.

Fresh Proceedings:
The firm has submitted reply for above queries as under -

Product Name	DRAP Query	Novartis Response
Sandostatin 0.5mg/ml Ampoule (Reg No. 086485) Sandostatin 0.05mg/ml Ampoule (Reg No 013473) Sandostatin 0.1mg/ml Ampoule (Reg No 013472)	1. Clarification regarding import of these products in the name of M/s Novartis Pharma AG Basel, Switzerland while as per available record M/s Sandoz Pharma Ltd Basel, Switzerland is the manufacturer.	Please note that Sandoz and Ciba Geigy were merged in 1996. We informed to ex-Ministry of Health regarding merger and submitted all relevant documents for change of title from Sandoz/Ciba-Geigy to Novartis Pharma AG. Attaching relevant documents that we had submitted to Health Authority for your reference.
	2. Submitted data regarding form-5F is of old manufacturing site.	We are submitting the following documents, showing our application is for new manufacturing site change: i. Manufacturer's name on CTD (32P31) ii. Form 5F (for all three strengths) iii. Already submitted CPP (for all three strengths) iv. Already submitted LoA.

Decision 85th PRVC.
On the recommendations of the committee, Chairman Registration Board considered and decided to refer the case to Registration Board.

Decision 323:
Registration Board considered the request and decided to refer to seek legal opinion as per above facts.

Case No. 02. ELI LILLY PAKISTAN'S REQUEST TO MAKE LABELING WEBSITE LIVE WITH THEIR CURRENT APPROVED LEAFLETS/PRESCRIBING INFORMATION.

The subject case was discussed in M-321 meeting of Registration Board and deferred as under: -

Eli Lilly Pakistan submitted application on 25-Aug-2022 for approval to make the website (www.mealabels.lilly.com) live and accessible to public/HCPs having their current approved Leaflets/Prescribing Information of their products:

E-Labeling is the dissemination of approved product information, via an electronic method (such as through a machine-readable QR code or URL) to the healthcare providers and patients.
With e-labeling, public/HCPs will have access to the most updated product information immediately after DRAP's approval/Notification.

In the below table, they further elaborated the benefits of e-labeling when it comes to patients, pharmacists and doctors:

Patient	Pharmacist	Doctor
❖ Access to the latest product information immediately after DRAP approval/Notification ❖ Product in the market will include the latest information	❖ Ability to access the locally approved product information without having to open the pack with the QR Code	❖ Providing a repository for doctors to reach local approved product information
Better readability and searchability of information		

Eli Lilly is implementing e-labeling across the Middle East countries through the addition of a QR code and a website URL to the product outer pack and physical leaflet.
Accordingly, once they got this 'website go live' approval, they will start notifying to DRAP artworks of their products by adding the QR codes and the website URL on the outer packs and leaflets.
Recently they have received approval to make their website Live from Lebanon and UAE Health Authorities.
They will not be eliminating the physical leaflet at this stage. The website will be updated right after new product information is approved by DRAP, allowing immediate implementation of label updates.
It is confirmed by the company that the website will only hold product information on the Pakistan pages that are already approved/Notified to DRAP.
Website layout also submitted with relevant pages to Pakistan.
Submitted for the recommendation of the Board for approval to make www.mealabels.lilly.com Labeling website Live with their current approved Leaflets/Prescribing Information.

Decision M-321: Registration Board considered and deferred for further deliberation.
Registration Board was apprised that e-labeling will be done by manufacturer for Middle East countries through the addition of a QR code and a website URL to the product outer pack and they will not eliminate the physical leaflet at this stage. After this 'website go live' approval, they will start notifying to DRAP artworks of their products by adding the QR codes and the website URL on the outer packs and leaflets. Further they apprise the Board, regarding approval to make their website Live from Lebanon and UAE Health Authorities.

Decision: Registration Board deliberated that request is not contradictory to drugs (Labelling & Packing) rules, 1976 and thus the Board approved firm's request.

Case No.03:- <u>REQUEST OF M/S HAJI MEDICINE CO., RAWALPINDI FOR INCREASE IN SHELF LIFE OF REGISTERED PRODUCT</u>.

The subject case was discussed in 29th PRVC, 41st meeting of PRVC & 69th PRVC, 316th meeting of Registration Board and deferred as per following details:-A

M/s. Haji Medicine Co., B-327, Iqbal Road, Rawalpindi has requested for increase in shelf life of registered product from 2 years to 60 months as per following details.

Reg. No.	Name/ Composition	Name of Manufacturer (as per registration letter)	Name of Manufacturer / PLH (as per COPP)	Initial registration with renewal	Remarks
I	I	III	IV	V	VI
052244	Setrovel Solution for Injection.	**Manufacturer:-** M/s Novell Pharmaceutical	**Manufacturer &**	25-10-2008	Dy. No.533 R&I dated 17-06-2014,

	Each ml contains:- Tropisetron Hydrochloride equivalent to 1.00mg	Laboratories, Indonesia.	**Product License Holder:** PT. Novell Pharmaceutical Laboratories JI. Wanaherang No.35, tlajung Udik, Gunung Putri Bogor 16962, Indonesia.	Last renewal date 21-05-2018	Dy. No.136 R&I dated 19-08-2014, Dy. No.669 R&I dated 11-09-2014, Dy. No.1162 R&I dated 19-11-2018& Dy. No.2299 R&I dated 01-04-2019 As per COPP shelf life is 60 months.

The firm has submitted the following supporting documents:-

a. Requisite fee of Rs.5000/-
b. Application on Form 5A.
c. Copy of registration letter with complete renewal trail.
d. Copy of valid DSL.
e. Stability data for Zone IV B of 3 batches.
f. Original & legalized COPPs issued by Indonesian Authority.
g. Justificaiton for increase in shelf life (3 stability batch data are provided).
h. "We conduct the stability study in storge conditions 30±2˚C, 75±5& RH following the condition for the climate zone IV-B which harsher/more extreme than the conditions requested (IV-A 30±2˚C, 65±5& RH). Also, storing product with the same temerature but different RH does not give specifically impact to the bulk contained in the ampules because RH can't penetrate directly into glass ampules. And it can be seen in the stability studies report that the reslut for the stability studies for 60 months are still complies with the specification therfore, it can be expected that the result will still be similar if it is conducted in less extreme condition (Zone IV-A)".
i. Undertaking that informaiton is true and correct.

Decision 29th PRVC:

Deferred for the submission of SmpC clearly mentioning the shelf-life of the innovator's product approved in any Reference Regulatory Authority.

Fresh Proceedings:

The firm has submitted as under: -

As per wikipedia there are two brand leaders in Tropisetron i.e. Navoban (Manf. By Novartis) and Setrovel (Manf. By PT Novell Pharmaceuticals Indonesia). Snap shot of said page from Wikipedia is attached and you can find the same through the following wbsie link.

http://en.Wikipedia.org/wiki/tropisetron

Novartis has withdrawan marketing of Navoban from Europe, USA and Austrialia etc and hence it has very limited availability throughout the owrld. Resultanly there is no avaible current data of Navoban on US-FDA, UK-MHRA and TGA-Australia etc.

In the absence of Navoban, now setrovel is the brand leader of Tropisetron Injction and any shelf life stability studies conducted by the manufacture of Strovel i.e. P Novell Pharmaceuticals Indonesia shall be acceptable as Industry Norm.

"AS we have already provided shelf life stability studies of Setrovel Injection for 05 years and CoPP of Setrovel Injection for 05 years shelf life issued by Indonesian Health Ministry and Attested by Embassy of Pakistan Jakarta so kindly approve extension of shelf life of Setrovel Injection from 02 Years to 05 years" As per Zone IV-B.

Decision 41st PRVC:
Deferred for final reminder for the submission of SmpC clearly mentioning the shelf-life of the innovator's product or any other regulatory document confirming proposed shelf life of the product approved in any Reference Regulatory Authority.

Fresh Proceedings:

The firm has submitted their reply as under: -

Please note that all comparative brands of Tropisetron including brand leader Navoban have discontinued this product and hence no comparative data is currently available in Reference Regulatory Authorities. Subsequently our brand i.e. Injection Setrovel is current brand leader of Tropisetron.

Secondly, Indonesian drug regulatory authority i.e. National Agency of Drug and Food control (NADFC) indonesia is a member of PIC/S since 2012. The pharmaceutical inspection convention is an international body for mutural recognition of inspections in respect of pharmaceutial products.

Therefore, it is obligatory upon DRAP to honor the recommendations of NADFC indonesia to increse the shelf life of Inj. Setrovel to 05 years.

NADFC Indonedia has already thoroguhly scrutinized the Zone 4 stability studies reltaing to Inj. Setrovel conducted by PT Novell Pharmaceutical Labortories, Indonesia and subsequently allowed them to increase the shelf life to 05 years.

Decision 69th PRVC
The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee & decided to defer for the submission of shelf-life of the innovator's product or any other regulatory document confirming proposed shelf life of the product approved in any Reference Regulatory Authority.

Fresh Proceedings by the firm:
Innovator's Product i.e. Navoban was manufactured by Novartis but Novartis has discontinued its manufacturing for last many years.
No other comparative brand is currently available in the world. No data of this product is available in any RRA.
Our brand i.e. Setrovel is manufactured by PT Novell Pharmaceutical Laboratories, Indonesia. Setrovel is currently brand leader of this product in the world.
We have already submitted 05 years stability studies data of Setrovel that has been approved by National Agency of Drug and Food Control (NADFC) Indonesia. NADFC Indonesia is member of PIC/S.

Decision 76th PRVC:
The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee & decided to refer the case to Registration Board.

Decision M-316:
Registration Board considered and decided to advise the firm to submit impurity profile and degradation data of the finished drug product upto assigned shelf life.

Fresh Proceedings by the firm:
The firm has submitted impurity profile and degradation data of Setrovel Injection over shelf life of 05 years.

Decision: Registration Board considered and approved the firm request for increase in shelf life from 02 years to 05 years as per following details: -

Reg. No.	Name of Drug/Composition	Name of Manufacturer & Product License Holder	New Approved Shelf Life
052244	Setrovel Solution for Injection. Each ml contains:- Tropisetron Hydrochloride equivalent to 1.00mg	PT. Novell Pharmaceutical Laboratories JI. Wanaherang No.35, tlajung Udik, Gunung Putri Bogor 16962, Indonesia.	05 Years

Case No.04: <u>REQUEST OF M/S NOVARTIS PHARMA FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.</u>

M/s Novartis Pharma Pakistan has submitted request for cancellation of registration of imported drug as per following details.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	Oxytocin 5 i.e haxal injection Each ampoule contains:- Synthetic oxytocin…5iu (USP Specifications)	080164	Due to global directives as we have divested this portfolio in Pakistan.	Oxytocin-5 by M/s Amaan Pharma. Syntox by M/s Brookes Pharma. Syntoxin by M/s Swiss Pharma. Synyomax by M/s Indus Pharma.

SOP Requirement	Firms Response
Application.	Application with a fee Rs.7,500/- for each product.
Copy of registration letter.	Copy of registration letter.
Justification.	As mentioned above.
List of alternatives brands/ FPPs available in the country.	As mentioned above.
An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Provided by the firm.

Decision: Registration Board did not accede to the request of M/s Novartis Pharma Pakistan for license/registration withdrawal of Oxytocin 5 i.e haxal injection (Reg. No.080164). The Board further decided as under:

iii. Rregistration holder will be directed to continue import in compliance with the conditions of rregistrations under Rule 30 of Drugs (L, R & Advertising) Rules, 1976 and also ensure regular and adequate supply of above-mentioned products to avoid their shortage in the market.

iv. **The matter will also be deliberated with "Committee on Availability of Life Saving Drugs" and outcome will be shared with Registration Board for consideration.**

Case No.05: <u>REQUEST OF M/S ROCHE PAKISTAN LIMITED FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS</u>

M/s Roche Pakistan Ltd, 37-B, 1st Floor Block-6 PECHS, Karachi has submitted request for cancellation of registration of imported drug as per following details.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	Xeloda Tablets Each tablet contains:- Capecitabine….500mg	027375	We would like to inform you that Roche has divested the rights of Xeloda in certain countries including Pakistan.	Capegard 500mg by M/s AJ Mirza Pharma. Xelocel 500mg by M/s Hakimsons Impex. Citabin 500mg by M/s Revive Health Care. Relicitabine 500mg by M/s Helix Pharma. Xelobig 500mg by M/s The Searle Company Ltd.

SOP Requirement	Firms Response
Application.	Application with a fee Rs.7,500/- for each product.
Copy of registration letter.	Copy of registration letter.
Justification.	As mentioned above.
List of alternatives brands/ FPPs available in the country.	As mentioned above.
An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Provided by the firm.

Decision: Registration Board did not accede to the request of M/s Roche Pakistan Ltd, 37-B, 1st Floor Block-6 PECHS, Karachi for license/registration withdrawal of Xeloda Tablets (Reg. No.027375). The Board further decided as under:

i. **Rregistration holder will be directed to continue import in compliance with the conditions of rregistrations under Rule 30 of Drugs (L, R & Advertising) Rules, 1976 and also ensure regular and adequate supply of above-mentioned products to avoid their shortage in the market.**
ii. **The matter will also be deliberated with "Committee on Availability of Life Saving Drugs" and outcome will be shared with Registration Board for consideration.**

Case No.06: <u>REQUEST OF M/S SANOFI-AVENTIS PAKISTAN LIMITED FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.</u>

M/s Sanofi-aventi Pakistan Ltd, Plot No.23, Sector No.22, Korangi Industrial Area, Karachi has submitted request for cancellation of registration of imported drug as per following details.

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	Tavanic I.V. Infusion Each 100ml contains:- Levofloxacin….500mg	021150	We have been informed by the Manufacturing site thaty they have decided to withdraw registration of Tavanic IV Infusion.	Leflox Infusion IV 500mg/100ml by M/s Getz Pharma. Effiflox Infusion IV 500mg/100ml by M/s Sami Pharma. Starlev Infusion IV 500mg/100ml by M/s Indus Pharma.

SOP Requirement	Firms Response
Application.	Application with a fee Rs.7,500/- for each product.
Copy of registration letter.	Copy of registration letter.
Justification.	As mentioned above.
List of alternatives brands/ FPPs available in the country.	As mentioned above.
An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Provided by the firm.

Decision: Registration Board did not accede to the request of M/s Sanofi-aventi Pakistan Ltd, Plot No.23, Sector No.22, Korangi Industrial Area, Karachi for license/registration withdrawal of Tavanic I.V. Infusion (Reg. No.021150). The Board further decided as under:

i. **Rregistration holder will be directed to continue import in compliance with the conditions of rregistrations under Rule 30 of Drugs (L, R & Advertising) Rules, 1976 and also ensure regular and adequate supply of above-mentioned products to avoid their shortage in the market.**
ii. **The matter will also be deliberated with "Committee on Availability of Life Saving Drugs" and outcome will be shared with Registration Board for consideration.**

Case.No.07. <u>REQUEST OF M/S BAYER PAKISTAN (PVT) LIMITED FOR CHANGE IN MANUFACTURING SITE & PACKAGING SITE ALONGWITH CHANGE IN ADDRESS OF IMPORTER AND REDUCTION IN SHELF LIFE (PRODUCT STATUS CHANGE FROM BULK IMPORT TO FINISHED IMPORT).</u>

M/s Bayer Pakistan (Pvt.) Ltd. Plot No. 23, Sector No.22 Korangi Industrial Area, Karachi has submitted request for change in manufacturing site & packaging site along with change in address of importer and reduction in shelf life (product status change from bulk import to finished import). Details are as under: -

Detail of change in Importer

Previous Name & address of Secondary Packaging and Imported by:	Proposed Name & address of Importer (as per DSL valid upto 05-07-2024)
M/s Bayer Pakistan (Pvt.) Ltd, 108, Kot Lakhpat Industrial Estate, Lahore..	M/s Bayer Pakistan (Pvt.) Ltd. Plot No. 23, Sector No.22 Korangi Industrial Area, Karachi **Godown address:**

	Plot No.1-D-22 and 1-D-23, Sector 30, Korangi Industrial Area, Karachi

Details of Product;

Reg. No.	Name & Composition of Drug / address	Detail of approved Sites as per approval (05-06-2017)	Detail of approved Sites as per CoPP
018207	Climen Tablet Contains: Calendar-pack containing 11 tablets of 2mg estradiol valerate each plus 10 tablets of 2mg estradiol valerate and 1mg cyproterone acetate each	**Name & Address of Manufacturer:** M/s Delpharm Lille SAS Parc d'Activites Roubaix-Est 22 Rue de Toufflers CS 50070 59452 Lys-Lez-Lannoy, France	**Product License Holder:** M/s Jenapharm GmbH & Co. KG Otto Schott-Strasse 15 07745 Jena, Germany. **Bulk Manufacturer, Packaging and final release:** M/s Bayer Weimar GmbH & Co. KG Dobereinerstrasse 20 99427 Weimar,Germany.
		Previous approve shelf life 60 months (not mentioned in Reg. Letter)	**Proposed shelf life** 36 months

The firm has submitted the following supporting documents: -

a) Fee of Rs.150,000/- for above product.
b) Copy of registration letter issued on 27-09-1995.
   - Approval for import in bulk and repacking locally on 18-01-1996
   - Change of name of Manf. from Schering S.A. Franche to Delpharm Lille S.A.S France on 19-07-2008.
   - Approval for change of manufacturer address on 05-06-2017.
   - Approval for change of title as M/s Bayer Pakistan (Pvt) Ltd, Lahore on 12-12-2018
   - Renewal due on 26-09-2020 (as per Reg. letter).
   - Renewal submit on 08-06-2020.
c) Copy of valid Drug Sale License (05-07-2024).
d) Original & Legalize CoPP.
e) Original Sole Agency Declaration Letter.
f) Justification for change in manufacturing site along with change in status from bulk to finished import.
g) An undertaking.

Decision: Registration Board considered and approved the firm request for change in manufacturing site & packaging site along with change in address of importer and reduction in shelf life (product status change from bulk import to finished import) as per following details: -

Detail of change in Importer

Previous Name & address of Secondary Packaging and Imported by:	Proposed Name & address of Importer (as per DSL valid upto 05-07-2024)
M/s Bayer Pakistan (Pvt.) Ltd, 108, Kot Lakhpat Industrial Estate, Lahore..	M/s Bayer Pakistan (Pvt.) Ltd. Plot No. 23, Sector No.22 Korangi Industrial Area, Karachi **Godown address:** Plot No.1-D-22 and 1-D-23, Sector 30, Korangi Industrial Area, Karachi

Details of Product;

Reg. No.	Name & Composition of Drug / address	Detail of approved Sites as per approval (05-06-2017)	Detail of approved Sites as per CoPP
018207	Climen Tablet Contains: Calendar-pack containing 11 tablets of 2mg estradiol valerate each plus 10 tablets of 2mg estradiol valerate and 1mg cyproterone acetate each	**Name & Address of Manufacturer:** M/s Delpharm Lille SAS Parc d'Activites Roubaix-Est 22 Rue de Toufflers CS 50070 59452 Lys-Lez-Lannoy, France	**Product License Holder:** M/s Jenapharm GmbH & Co. KG Otto Schott-Strasse 15 07745 Jena, Germany. **Bulk Manufacturer, Packaging and final release:** M/s Bayer Weimar GmbH & Co. KG Dobereinerstrasse 20 99427 Weimar,Germany.
		New Approved Shelf Life 36 months	

Case No. 08. <u>GUIDANCE REQUIRED REGARDING COMPLIANCE WITH PHARMACOPEIAL SPECIFICATIONS.</u>

Director Drug Testing Laboratory Faisalabad vide letter on subject "Guidelines Required regarding compliance with Pharmacopeial specifications" dated 06-09-2022, in which he has informed that the timeline given by the Registration Board has been ended on 26th April 2022. In the light of the decision of the Registration Board DTL Faisalabad requested the guidance on following:

Sr.#	DTL Faisalabad guidance requested points
1.	Manufacturers/ Registration holders of drug products that are still (May, 2022 onward) manufacturing their products as per Manufacturer's /Innovator's Specifications despite the availability of the monographs in Pharmacopoeia and are unable to provide DRAP's approval shall be Misbranded?
2.	If product specifications mentioned on the label are MS/Innovator's Specs and DRAP has not yet granted the approval though monograph is available in official pharmacopeias, which specifications would be opted to test/analyze the said product?
3.	In United States Pharmacopeia (USA), several tests are mentioned in dissolution test of various monographs and USP stated that except the test I, the Dissolution test number should be mentioned on the label of the product, If dissolution test no. is not printed on the label and manufacturer specify USP test 2 or test 3 in its method of analysis, on which dissolution test, the said product should be tested. And whether product would be declared misbranded or not.

Registration Board in its 317th meeting held on 16-17th May 2022 decided not to further extend timelines for compliance with pharmacopeial specifications.

Pharmaceuticals firms started to apply for specifications as per decision of Registration Board and PE&R division processed many of these applications and a number of applications are still under the process of evaluation and final approval.

Proceedings:

The Board was appraised that PE&R Division has already decided/disposed of cases applied for the change in specifications as per direction of the Board.

Decision of 321st Meeting: Keeping in view above proceedings, Registration Board decided to advise the DTL Faisalabad to proceed in accordance with Drug Specification Rules 1978 for queries at S.No.1 and 2 while query at SNo.3 will be deliberated in the forthcoming meeting of Registration Board.

Matter related to specifications discussed in several meetings of the Registration Board as some products have been declared mis-branded by Drug Testing Laboratories as their official monographs

have been included in pharmacopeia and registration holders mentioned manufacturer's specifications on unit cartons.
In 316th meeting of Registration Board Dr.Muhammad Munawar Hayat, Director, DTL Punjab Opined that Registration Board is not competent to relax the compliance of pharmacopoeial specification, as these are Rules (Drugs Specification Rules, 1978) made under the Drugs Act, 1976. Director DTL Faisalabad query regarding dissolution test discussed and deliberated that several product have more than one dissolution tests in their monographs.
Example 1:
Omeprazole Delayed Release Capsules USP has two different dissolution tests namely Dissolution Test 1 & Test 2. Furthermore, pharmacopeia has mentioned that:
"Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*"
Example 2:
Esomeprazole Magnesium Delayed-Release Capsules USP has four different dissolution tests namely Dissolution Test 1, Test 2, Test 3 & Test 4.
Furthermore, pharmacopeia has mentioned that:
Test 2: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 2*
Test 3: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 3*.
[NOTE—Use only glass bowls]
Test 4: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 4*
If dissolution test specifically is not mentioned than definitely manufacturer will follow test 1

Decision: **Keeping in view above proceedings, Registration Board decided to issue advisory to mention the dissolution test Number on the immediate container of product for dissolution tests No 2,3 or 4 as per requirement of USP otherwise it would be presumed that dissolution test No.1 shall be performed on the finished product.**

Case No: 09 **M/S SANOFI-AVENTIS PAKISTAN REQUESTED FOR EXTENSION IN EXEMPTION FROM LABELING TEXT ON - FLUDARA 50MG (REG. NO. 088890) POWDER FOR SOLUTION FOR INJECTION/INFUSION & AUBAGIO 14MG TABLET (REG. NO. 105585).**

M/s Sanofi-aventis Pakistan requested that **Fludara** is indicated for the treatment of B-cell chronic lymphocytic leukaemia (CLL) in adult patients with sufficient bone marrow reserves and low-grade Non-Hodgkin's Lymphoma. Since Fludara is a highly specialized **Life Saving Medicine** and **critically needed essential drug** provided to institutes therefore, it is our social responsibility to make it available for patients in need.

Fludara is being manufactured and primarily packaged in large volume at the source point in Germany, then it is supplied to United Kingdom for Secondary Packaging from where supplies are made to various countries as per their needs.

SALES RECORD:

The sales record of Fludara is mentioned below since the transfer of its registration in name of sanofi-aventis Pakistan limited:

Product name	**No of unit packs imported**			**No of unit packs sold**			
Fludara	2019	2020	2021	2019	2020	2021	2022
	60	**60**	**60**	**37**	**45**	**68**	**24**

***6 Packs used for QI sampling**

Fludara is purely used by the Government and Private institutes. Below is the list of institutions where Fludara Injection is being supplied;

S. #	Institutes	City
1	Armed Forces Bone Marrow Transplant Centre	Rawalpindi
2	Combined Military Hospital (CMH)	Rawalpindi
3	MINAR	Multan
4	Shaukat Khanum Memorial Lahore	Lahore
5	Hameed Latif Hospital	Lahore
6	INMOL Cancer Hospital	Lahore
7	Children's Hospital	Karachi
8	Agha Khan Hospital	Karachi

The firm has submitted the following documents:

i. An undertaking that to print the Urdu Text, Registration Number and Maximum Retail Price (MRP) on each pack of above product at their Karachi site bearing DML No. 000007, before releasing the goods into the market.
ii. Copy of Registration letter
iii. Copy of DML
iv. Fee 10,000/-

Decision: Registration Board acceded to the request for import of already registered products (Fludara 50mg Powder for solution for Injection/Infusion (Reg. no. 088890) & Aubagio 14mg tablet (reg. No. 105585) in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000007) to comply requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) year only. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

Case.No.10: <u>REQUEST OF M/S VIKOR ENTERPRISES PVT LTD, KARACHI FOR REGISTRATION OF DRUGS TO THEIR NAME.</u>

M/s Vikor Enterprises (Pvt) Ltd, Plot No. Z2-A, SITE, Manghopir Road, Karachi has submitted an application for Registration of following already registered products from M/s GlaxoSmithKline (Pakistan) Ltd, 15 West Wharf Karachi to their name. Detail of each proposed product is as under: -

Product-1: Duofilm Lotion (Reg.No.005032)		
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**
1.	Product Name/ Composition	**As per approval** Duofilm Lotion **As per CoPP** Duofilm, Cutaneous Lotion Each 10g solution contains: Salicylic acid…1.67g Lactic acid….1.5g
	Reg. date / renewal status	a) Copy of Reg. Letter **29-12-1979** (M/s Fazal Din & Sons, Lahore). b) Copy of transfer letter dated **23-08-2011** (from M/s Stiefel Labs Pak (Pvt) Ltd, Lahore to M/s GSK Pak Ltd, 35-Dockyard Road, West Wharf, Karachi). c) Change of source approval letter dated **20-05-2016** (from M/s Stiefel Labs Ireland to M/s Famar Nederland B.V, Netherlands). d) Registration Board in its 320th meeting renewal granted w.e.f 20.05.2021 to 19.05.2026.

	Name and address of Applicant(Transferee)	M/s Vikor Enterprises (Pvt) Ltd, Plot No. Z2-A, SITE, Manghopir Road, Karachi.
	Name of Transferor	M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road West Wharf, Karachi.
	Detail of Drug Sale License	**DSL No.193 (valid upto 08-04-2023)** **Address:** **Godown address:** M/s Vikor Enterprises (Pvt) Ltd, Plot No.F-24, SITE, Karachi.
	Name and address of Manufacturer / Product License Holder	**As per approval (m/s GSK apply for change of site)** **Manufacturer, Release by & Packaging:- (as apply)** Delpharm Bladel B.V. Industrieweg 15531 AD Bladel The Netherlands. **As per CoPP (BA 1221-098):** **Product License Holder:** M/s STADA Consumer Health Deutschland GmbH Stadastrasse 2-18 61118 Bad Vilbel, Germany **Manufacturer.** M/s Delpharm Bladel B.V. Industrieweg 1 5531 AD Bladel The Netherlands.
	Name of exporting Country	Germany
	Diary No. & Date of R& I	Dy. No. 33214 Dated 18/11/2022.
	Finished Product Specification	---
	Shelf life	As per CoPP 30 Months
	MRP/Pack Size	As per new request/dossier Rs.384.52/15ml

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Fee of Rs.150,000/- for each product.
b) Applications on Form-5F.
c) Original legalized CoPP issued by Germany.
d) Original Legalized Termination/cancellation/authorization letter & NOC from STADA Arzneimittel AG/ GSK Pakistan Ltd, Karachi dated 27-01-2022.
e) An undertaking provided

Decision 323: Keeping in view the above position, Registration Board decided as follow;

a. Cancellation of registration of following product from the name of M/s GlaxoSmithKline (Pakistan) Ltd, 15 West Wharf Karachi.

S. No	Reg. No.	Name of product
1.	**005032**	**Duofilm Lotion**

b. Approved the registration of above product in the name of M/s Vikor Enterprises (Pvt) Ltd, Plot No. Z2-A, SITE, Manghopir Road, Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).

c. A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of the said product.

Case.No.11: <u>REQUEST OF M/S ELI LILLY PAKISTAN LTD, KARACHI FOR UPDATE LEAFLET FOR NEW INDICATION OF REGISTERED PRODUCTS.</u>

M/s Eli Lilly Pakistan Ltd, Karachi has submitted request for update leaflet for new indication for their registered products. Details of products are as under: -

S. N	Reg. No.	Name of Drug(s) & Composition.	Manufacturer & Marketing Authorization Holder
1	110528	Olumiant 2mg Tablet Each film coated tablet contains: Barcitinib……2mg (Innovator's Specification)*	**Product License Holder:** Eli Lilly Nederland B.V., Papendorpseweg 83, 3525 BJ Utrecht, The Netherlands. **Manufacturer & Quality Control Site:** M/s Lilly del Caribe, Inc., 12.6Km, 65th Infantry Road, Carolina, 00985 Puerto Rico (Site also responsible for Quality Control). **Packing and Released Site:** Lilly S.A., Avda. De la Industria 30, 28108 Alcobendas, Madrid Spain. (Site responsible for batch release in EU, primary and secondary packaging).
2	110529	Olumiant 4mg Tablet Each film coated tablet contains: Barcitinib……4mg (Innovator's Specification)*	-do-

Existing Indications	New Indications
Rheumatoid arthritis Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate (see sections 4.4, 4.5 and 5.1 for available data on different combinations). Atopic dermatitis Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy.	Rheumatoid arthritis Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate (see sections 4.4, 4.5 and 5.1 for available data on different combinations). Atopic dermatitis Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy. Alopecia areata Baricitinib is indicated for the treatment of severe alopecia areata in adult patients

Firm has submitted following documents: -

a) Deposit Slip of Rs.15,000/= as fee (Rs.7500/= for each product) with deposit slip No. 0777599002, and 05613544259 dated: 29-Aug-2022, additional fee Rs. 2500/- for each product 08-11-2022.
b) Copy of registration letter
c) Justification of proposed change is mentioned above with tabulated new and all indications.
d) Copy of EMA approval
e) Copy of existing leaflet
f) Copy of proposed annotated and clean leaflet

Decision: Registration Board considered and approved the firm request for new indications as per following details: -

Name of Drug(s) & Composition/Reg. No.	New Indications
Olumiant 2mg Tablet Each film coated tablet contains: Barcitinib……2mg **Reg. No. 110528**	<u>Rheumatoid arthritis</u> Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate (see sections 4.4, 4.5 and 5.1 for available data on different combinations). <u>Atopic dermatitis</u> Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult patients who are candidates for systemic therapy. <u>Alopecia areata</u> Baricitinib is indicated for the treatment of severe alopecia areata in adult patients
Olumiant 4mg Tablet Each film coated tablet contains: Barcitinib……4mg **Reg. No. 110529**	

Case No.12: <u>REQUEST OF M/S HOSPITAL SUPPLY CORPORATION, KARACHI FOR CHANGE OF ADDRESS OF MANUFACTURING SITE (MEDICAINE INJECTION REG. NO.023645)</u>

M/s Hospital Supply Corporation, Karachi has applied for approval of change of address of manufacturing site for their already registered product medicaine injection (Reg. No. 023645) as per details given below:

Reg. No.	Name & Composition (as per approval)	Existing approved Manufacturing Site (as per approval)	New Proposed Site / Manufacturer & Product License Holder (as per COPP)
023645	**As per Approval** Kwang Myung Lidocaine HCL Injection. Each 1.8ml cartridge contains:- Lidocaine Hcl USP 36mg. Epinephrine Bitrtrate USP 0.324mg (Eq to 0.018mg of Epinephrine) **As per Transfer letter** Kwang Myung Lidocaine HCL Injection (Medicaine Injection)	M/s Kwang Myung Pharm. Co. Ltd 907, Sangshin – RI, Hyangnam – Myun, Hwaseong-Kun, KyuncGI-Do, Rep. of Korea.	**Manufacturer & Product License Holder: -** M/s Huons Co., Ltd, 100 Bio Valley-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea

The firm has submitted the following supporting documents: -

1. Fee of Rs. 100,000/- dated 09-07-2019.
2. Application on Form-5F
3. Copy of initial registration letter 26-05-1999 & transfer letter 15-05-2000 with renewal last renewal status.

4. Original & legalized COPP with free sale status of the product.
5. Original & legalized GMP certificate
6. Original & legalized Free Sale Certificate.
7. Original agent agreement
8. Letter of Authorization from product license holder.
9. Copy of DSL.
10. Prescribed undertaking.

Decision M-296: Registration Board approved the change of address of manufacturing site of following registered product medicaine injection (Reg. No. 023645) subject to policy for inspection of manufacturer abroad for imported finished drugs. Other terms and conditions will remain the same.

Reg. No.	Name & Composition (as per approval)	Existing approved Manufacturing Site (as per approval)	New approved Site / Manufacturer & Product License Holder (as per COPP)
023645	**As per Approval** Kwang Myung Lidocaine HCL Injection. Each 1.8ml cartridge contains:- Lidocaine Hcl USP 36mg. Epinephrine Bitrtrate USP 0.324mg (Eq to 0.018mg of Epinephrine) **As per Transfer letter** Kwang Myung Lidocaine HCL Injection (Medicaine Injection)	M/s Kwang Myung Pharm. Co. Ltd 907, Sangshin – RI, Hyangnam – Myun, Hwaseong-Kun, KyuncGI-Do, Rep. of Korea.	**Manufacturer & Product License Holder: -** M/s Huons Co., Ltd, 100 Bio Valley-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea

The comments /remarks of Legal Affair Division are as under:

"The instant case is of import of un-registered drug from a manufacturer which was not approved by the Registration Board yet. Moreover, mere approval by the Registration Board does not create any vested right of registration for any company / firm till the registration letter / post registration variation letter is issued. Therefore, the PE&R Division may process the case for prosecution of import of unregistered drug".

Area FID Report

It is pertinent to mention that the clearance of the product under question was given in light of registration letter no.F.1-16/93-Reg-I dated 4th November, 2004 in which the name of manufacturer was changed from M/s Kwang Myung Pharm.Co.Ltd: 907, Sangshin-ri, Hyangnam-Myun, Hwaseong-city, Kyunggi-do. Rep.of Korea to M/s Huons Co. Ltd Korea whereas the address of the manufacturer is not mentioned.

In the light of above it is established that M/s Hospital Supply Corporation Karachi has imported consignment of Medicaine Injection from the new source before getting the approval letter.

Decision: Registration Board deliberated on the opinion of the Legal Affairs Division to prosecute the firm for import of unregistered . The Board after deliberation decided to issue show cause notices to the firm M/s Hospital Supply Corporation, Karachi, under section 7 (11) read with 42 of the Drugs Act, 1976 for violation the condition of registration as reported by area FID.

As per decision, show cause notice issued to the firm vid F.No.3-4/2022-I&V-II(M-320)/Human Import dated 2nd December 2022

Proceeding and Decision:

Mr. Mahmood Feroz (Director) Hospital Supply corporation appeared before the Board and requested for issuance of variation of letter as per need of this medicine. Board inquired about the import of drug before official approval letter from new source but they did not reply satisfactory.

Registration Board after deliberation and keeping in view the above discussion decided as follows:

- **To prosecute the firm through its Directors/Management/Partners/Technical persons for violation of conditions of registration under section 7 (11) read with Rule 30 of the Drugs (L,R & A) Rules, 1976 under Drugs Act, 1976**
- **To issue variation letter to the importer as already approved by Registration Board.**

Case No.1 Renewal application under Drug (LR&A) Rules 1976 and SRO 1005(I)/2017.

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s. Amros Pharmaceuticals A96/, S.I.T.E. Super Highway, Karachi Pakistan					
1.	061124	Volvocef 125mg / 5ml Dry Suspension Each 5ml contains: Cephradine… 125mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Registration Board acknowledged the receipt of renewal application with prescribed fee under SRO 1005(I)/2017, However renewal letter shall be issued after the decision of Registration Board regrading confirmation of formulation in reference regulatory authorities.
2.	061125	Volvocef 250mg / 5ml Dry Suspension Each 5ml contains: Cephradine… 250mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.
3.	061126	Furox 250mg / 5ml Dry Suspension Each 5ml contains: Cefuroxime as Axetil… 125mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025. .
4.	061127	Volvocef Capsule Each capsule contains: Cephradine… 250mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.
5.	061128	Volvocef Capsule 500mg Each capsule contains: Cephradine… 500mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.

				Rs.180,000/-	
6.	061129	Rofil 400mg Capsule Each capsule contains: Cefixime as Trihydrate… 400mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025. The specifications shall be granted as per decision in 313rd meeting of Registration Board.
7.	061130	Furox 125mg Capsule Each capsule contains: Cefuroxime as Axetil… 125mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.
8.	061131	Furox 250mg Capsule Each capsule contains: Cefuroxime as Axetil… 250mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.
9.	061132	Rofil 100mg / 5ml Dry Suspension Each 5ml contains: Cefixime as Trihydrate… 100mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.
10.	061133	Rofil 200mg / 5ml Dry Suspension Each 5ml contains: Cefixime as Trihydrate… 200mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.
11.	061134	Rofil 200mg Capsule Each capsule contains: Cefixime as Trihydrate… 200mg (USP Specifications)	15/02/2010	Dy. No. 4808 dated 12-02-2021 Rs. 10000/- & Dy No. 30307 Dated 25-10-2022 Rs.180,000/-	Renewal is granted w.e.f 15.02.2020 to 14.02.2025.
M/s. SPL pharmaceuticals Pvt Ltd, Plot no.4 Phase III, Hattar Industrial Estate, Hattar					
12.	068475	Azibron 250mg Tablet Each tablet contains:	26/03/2011	Dy No.12226 dated 23.04.2021 Rs. 10,000/- &	Renewal is granted w.e.f 26.03.2021 to 25.03.2026.

		Azithromycin (as dihydrate) ……...250mg (USP Specifications)		Dy. No.29373 Dated 17/10/2022 Rs.15,000/-	The formulation shall be corrected as film coated tablet
13.	068474	Gemset 320mg Tablet Each tablet contains: Gemifloxacin (As Mesylate) …….320mg (SPL Specifications)	26/03/2011	Dy No.12226 dated: 23.04.2021 Rs. 10,000/- & Dy. No.29373 Dated 17/10/2022 Rs.15,000/-	Renewal is granted w.e.f 26.03.2021 to 25.03.2026. The formulation shall be corrected as film coated tablet and firm shall submit reference of finished product specification along with prescribed fee as per decision of 295th meeting of Registration Board.
14.	068473	B.C-20 Tablet Each tablet contains: Piroxicam Beta-cyclodextrin…….20mg (SPL Specifications)	26/03/2011	Dy. No.12226 dated; 23.04.2021 Rs. 10,000/- & Dy. No.29373 Dated 17/10/2022 Rs.15,000/-	Renewal is granted w.e.f 26.03.2021 to 25.03.2026. The firm shall submit reference of finished product specification along with prescribed fee as per decision of 295th meeting of registration Board.
15.	068472	Lenova 500mg Tablet Each tablet contains: Levofloxacin Hemihydrate equivalent to Levofloxacin…….500 mg (SPL Specifications)	26/03/2011	Dy. No.12226 dated: 23.04.2021 Rs.10,000/- & Dy No.29373 Dated 17/10/2022 Rs.15,000/-	Renewal is granted w.e.f 26.03.2021 to 25.03.2026. The formulation shall be corrected as film coated tablet and firm shall submit reference of finished product specification along with prescribed fee as per decision of 295th meeting of registration Board.
16.	068471	Q-Flox 500mg Tablet Each tablet contains: Ciprofloxacin (as HCl)…..500mg (USP Specifications)	26/03/2011	Dy No.12226 dated 23.04.2021 Rs.10,000/- & Dy No.29373 Dated 17/10/2022 Rs.15,000/-	Renewal is granted w.e.f 26.03.2021 to 25.03.2026. The formulation shall be corrected as film coated tablet.
17.	068470	Act-onn Gel 0.5% Each 5gm contains: Piroxicam…….0.5% (USP Specifications)	26/03/2011	Dy No.12226 dated 23.04.2021 Rs.10,000/- & Dy No.29373	Renewal is granted w.e.f 26.03.2021 to 25.03.2026. The formulation shall be corrected as film coated tablet.

				Dated 17/10/2022 Rs.15,000/-	
18.	068469	SP Queens 4% Cream Each 5gm contains: Hydroquinone……4% (SPL Specifications)	26/03/2011	Dy No.12226 dated 23.04.2021 Rs.10,000/- & Dy No.29373 Dated 17/10/2022 Rs.15,000/-	Renewal is granted w.e.f 26.03.2021 to 25.03.2026. The formulation shall be corrected as film coated tablet and firm shall submit reference of finished product specification along with prescribed fee as per decision of 295th meeting of registration Board.

Case No.2 Renewal application of M/s Amros Pharmaceuticals A96/, S.I.T.E. Super Highway, Karachi Pakistan deferred in 316th meeting of Registration Board.

M/s Amros Pharmaceuticals Karachi informed that they have submitted late renewal application due some unavoidable circumstances and in future this mistake will not be repeated. The firm further informed that as under SRO 1005, the renewal application can be submitted within 01 year of the due date. Due to COVID situation most of our staff which was involved in regulatory submission was unavailable. As per SRO the due date for the renewal submission for Registration No.039355 & 039356 was 11.07.2021. But unfortunately, 10.07.2021 and 11.07.2021 was official holiday (Saturday Sunday) and for registration No.061861,061862,061863,061864,061865, & 061866 was 29.08.2021 but on 28.08.2021 & 29.08.2021 was holiday (Saturday Sunday) in this regard the renewal application was submitted on next working day. Accordingly, the case was considered in 316th meeting of Registration Board and Board decided as under:

"Keeping in view the stance of the firm as narrated in last column above, the renewal applications of above products are within one year after due date under SRO 1005(I)/2015. Registration Board directed M/s. Amrose Pharmaceuticals, A-96 SITE Karachi to submit differential fee under aforesaid SRO for onward consideration".

Now the firm has submitted the differential fee, details are as under:

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Remarks
M/s. Amros Pharmaceuticals A96/, S.I.T.E. Super Highway, Karachi Pakistan					
1.	039355	Amfic Cream Each gram contains: Fusidic Acid… 20mg	12.07.2005 Renewal granted: 12.07.2015	Dy No.30809 dated 12.07.2021 Rs. 30,000/- And Rs.150,000/- dated 16.09.2022	Renewal is granted w.e.f 12.07.2020 to 11.07.2025 The firm shall submit reference of finished of finished product specification along with prescribed fee

					as per decision of 295th meeting of Registration Board.
2.	039356	Amoivil Injection Each ml contains: Pheniramine Maleate…. 22.7mg	12.07.2005 Renewal granted: 12.07.2015	Dy No.30809 dated 12.07.2021 Rs. 30,000/- And Rs.150,000/- dated 16.09.2022	Renewal is granted w.e.f 12.07.2020 to 11.07.2025 The firm shall submit reference of finished of finished product specification along with prescribed fee as per decision of 295th meeting of Registration Board.
3.	061862	Bensol N Drop Each ml contains: Betamethasone Sodium Phosphate… 0.1% Neomycin Sulfate… 0.5% (Manufacturer Specifications)	30.08.2010	Dy No.30809 dated 30.08.2021 Rs. 15,000/- And Rs.160,000/- dated 16.09.2022	Renewal is granted w.e.f 12.07.2020 to 11.07.2025 The firm shall submit reference of finished of finished product specification along with prescribed fee as per decision of 295th meeting of registration Board.
4.	061863	Amrokort Injection Each ml contains: Triamcinolone Acetonide… 40mg (BP Specifications)	30.08.2010	Dy No.30809 dated 30.08.2021 Rs. 15,000/- And Rs.160,000/- dated 16.09.2022	Deferred for confirmation of manufacturing facility for injectable steroids.
5.	061864	Clav 375mg Tablet Each sugar-coated tablet contains: Amoxicillin as Trihydrate… 250mg Clavulanic Acid as Potassium… 125mg (USP Specifications)	30.08.2010	Dy No.30809 dated 30.08.2021 Rs. 15,000/- And Rs.160,000/- dated 16.09.2022	Renewal is granted w.e.f 12.07.2020 to 11.07.2025
6.	061865	Clav 625mg Tablet Each sugar-coated tablet contains: Amoxicillin as Trihydrate… 500mg Clavulanic Acid as Potassium… 125mg (USP Specifications)	30.08.2010	Dy No.30809 dated 30.08.2021 Rs. 15,000/- And Rs.160,000/- dated 16.09.2022	Renewal is granted w.e.f 12.07.2020 to 11.07.2025

7.	061866	Clav Tablet Each sugar coated tablet contains: Amoxicillin as Trihydrate… 875mg Clavulanic Acid as Potassium… 125mg (USP Specifications)	30.08.2010	Dy No.30809 dated 30.08.2021 Rs. 15,000/- And Rs.160,000/- dated 16.09.2022	Renewal is granted w.e.f 12.07.2020 to 11.07.2025
8.	061861	Clav Drops Each ml contains: Amoxicillin as Trihydrate… 500mg Clavulanic Acid as Potassium… 12.5mg (USP Specifications)	30.08.2010	Dy No.30809 dated 30.08.2021 Rs. 15,000/- And Rs.160,000/- dated 16.09.2022	Renewal is granted w.e.f 12.07.2020 to 11.07.2025

Case No.3 Renewal application under Drug (LR&A) Rules 1976 and SRO 1005(I)/2017.

The firm has informed that below mentioned application for renewal of Drugs under SRO 1005(I)/2017 dated 28th November, 2017 are yet to be considered. The firm further informed that majority of products applied were included in the 281st DRB meeting and renewal letter was issued but following products were not included in the agenda of meeting and hence renewal was not granted. Details are as under:

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad					
1.	025657	M-Butamol Tablets Each tablet contains: Salbutamol BP……..4mg	30.03.2000 PRV: **09.06.2005**	Rs.30000/- dated 29.11.2017	Deferred for submission of evidence of renewal of year 2010 for consideration under SRO 1005(I)/2017.
2.	021613	Irosul Tablet 200mg Each tablet contains: Ferrous Sulphate USP…..200mg	20.05.1998	Rs.30000/- dated 29.11.2017	Deferred for submission of following: i. Approval of transfer for registration from M/s Amson Farmaco Biologico Islamabad to M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad ii. Evidence of submission of

					renewal for year 2008
3.	25581	Amchoram-4 Tablet Each tablet contains: Chlorapheniramine Maleate BP……4mg	08.03.2000 PRV: **09.06.2000**	Rs.30000/- dated 29.11.2017	Deferred for submission of following: iii. Approval of transfer for registration from M/s Amson Farmaco Biologico Islamabad to M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad iv. Evidence of submission of renewal for year 2008
4.	021780	Amfer Tablet Each tablet contains Ferrous Fumarate USP……200mg	20.05.1998	Rs.30000/- dated 29.11.2017	Deferred for submission of following: v. Approval of transfer for registration from M/s Amson Farmaco Biologico Islamabad to M/s. Amson Vaccines & Pharma (Pvt) Ltd. Islamabad vi. Evidence of submission of renewal for year 2008

Case No: 4 Cancellation of Registration in 317th meeting of Registration Board of M/s. Jawa Pharmaceuticals (Pvt) Ltd.,112/10 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore. (DML No.000150).

It is submitted that below mentioned products were considered in 320th meeting of Registration Board and Registration Board advised RRR section to come up with renewal submission details of above products for the year 2021 at Sr. No. 1 and for year 2020 at Sr. No. 2-16. Accordingly, details have been checked and renewal application was submitted on 11.03.2021 for product at Sr. No. 2 and rest on 20.04.2020.

Sr. No.	Reg. No.	Product Name & Composition	Date of Reg/ PRV	Renewal Due Date	Renewal Application Submission Date	Renewal Status
1.	004712	Calamine Lotion Each 100ml contains: Calamine…15mg Zinc Oxide…5gm	27-03-1979 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
2.	004713	Amrid Syrup Each 5ml contains:	27-03-1979	22.03.2016	17-02-2016	

		Ammonium chloride …100mg Sodium Citrate….60mg Chlorpheniramine Maleate….2mg Ephedrine HCl….5mg Menthol….5ml	Transfer of Reg: **23.12.2006**			
3.	007873	Aminophylline 100mg Tablet Each tablet contains: Aminophylline….100mg	03-02-1985 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
4.	007874	M.Broplex Tablet Each tablet contains: Thiamine HCl….1mg, Riboflavin…..1mg Nicotinamide...15 mg	03-02-1985 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
5.	007875	Chlorpheniramine Maleate 4mg Tablet Each tablet contains: Chlorpheniramine Maleate….4mg	03-02-1985 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
6.	007876	Scabicid Lotion Contains: Benzyl Benzoate…..25%	03-02-1985 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
7.	007877	M. Brovit Syrup Each 5ml contains: Vitamin A 25000IU Vitamin D 250IU Thiamine HCl….0.55mg Nicotinamide…….5.5mg Riboflavin…...0.65 mg Ascorbic Acid….15mg	03-02-1985 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
8.	004954	Carminative Mixture Each 100ml contains: Sodium Bicarbonate…5gm	05-08-1979 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	

		Spirit Ammonia Aromatic…6.5ml Tr. Cardco….6.5ml Aqua Mentha Pip Conc… 4.8ml				
9.	004486	Chloroquine Phosphate Syrup Each 100ml contains: Chloroquine Phosphate eq. to Chloroquine Base…..40mg	20-11-1978 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
10.	004955	Ferrous Gluconate Syrup Each 5ml contains: Ferrous Gluconate...300mg	08-09-1979 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
11.	007794	M.Brozine Elixir Each 5ml contains: Promethazine HCl…...5mg	28-01-1985 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
12.	004953	Mephen Syrup Each 5ml contains: Diphenhydramine HCl…..13.5mg Ammonium Chloride…...131.5 mg	05-08-1979 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
13.	004432	Diatrin Suspension Each 30ml contains: Kaolin……5.832g Pectin…...0.130gm	30-09-1985 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
14.	004433	Tr. Benzoine Co Contains: Benzoin Crushed….10% Aloes BP……2% Tolu Balsam BPC…….40% Prepared Storax BPC…8% Spirit rectified…90%	22-11-1978 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	
15.	006603	Mandls Paint Each 100ml contains: Iodine….1.25gm Pot. Iodine…...2.5gm	23-11-1982 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	

		Peppermint Oil….0.4ml Alcohol 90%...4ml Water……...2.5ml Glycerine….100ml				
16.	006710	Gum Paint Each 100ml contains: Tr. Aconite….1% Tr. Myrrh….10% Tr. Iodine Mitis Rect……...4% Oil of clove……0.01% Menthol….0.01% Glycerine….25% Spt. Rectified…100ml	21-02-1983 Renewal granted: **28.04.2015**	27.04.2015	13-04-2015	

Decision of 317th meeting:

Registration Board cancelled the registration of above products as renewal applications were submitted after prescribed time period under rule 27 of Drug (LR&A) Rules 1976. Accordingly, cancellation letter was issued on 04 & 05th July 2022.

Reply of the firm:

Sr. No.	Reg. No	Name of product	Transfer of Reg /Issuance of renewal	Date of submission of renewal
1.	004713	Amrid Syrup (Ammonium Chloride Cough Syrup)	23.12.2006	17-02-2016
2.	007873	Aminophylline 100mg Tablet	Renewal granted till **28.04.2015** vide letter No. 11-17/2006-RRR dated 11.06.2009	13-04-2015
3.	007875	Chlorpheniramine Maleate 4mg Tablet	-do-	13-04-2015
4.	007874	M.Broplex Tablet	-do-	13-04-2015
5.	004712	Calamine Lotion	-do-	13-04-2015
6.	004954	Carminative Mixture	-do-	13-04-2015
7.	004486	Chloroquine Phosphate Syrup	-do-	13-04-2015
8.	004955	Ferrous Gluconate Syrup	-do-	13-04-2015
9.	007794	M.Brozine Elixir	-do-	13-04-2015
10.	004953	Mephen Syrup	-do-	13-04-2015
11.	007877	M.Brovit Syrup	-do-	13-04-2015
12.	004432	Diatrin Suspension	-do-	13-04-2015
13.	004433	Tr. Benzoine Co	-do-	13-04-2015
14.	006603	Mandls Paint	-do-	13-04-2015

15.	006710	Gum Paint	-do-	13-04-2015
16.	007876	Scabicid Lotion	-do-	13-04-2015

Firm has requested to review the above decision.

Decision: **Keeping in view the submission of approval of post registration variation and renewals by the firm as recorded above, the renewal applications for year 2015 and 2016 were submitted within time. Hence the cancellation letter issued vide letter No. F.3-8/2022-RRR (M-317) dated 04 & 05th July 2022 is hereby withdrawn *void ab initio.***

Case No.5 **Renewal application of Ribunal Suspension (078904) of M/s. Al-Fazal Pharma Industries (Pvt) Ltd.,16-Km Sheikhupura Road Lahore.**

The firm on 10.06.2020 submitted a letter regarding renewal of products including the said product and stated they are not able to submit these files within time due Covid-19 and requested to considered the current situation and renew them all. The fee and application on Form-5B was later on submitted on 15.09.2021 with Rs. 30,000/- fee. The firm further informed that they have submitted deposited the late fee for mentioned products. The delay is due to COVID-19 as the industry remains closed for few months in 2020. As opened they submitted the renewal with late fee in 2021. Accordingly, the case was considered in 316th meeting of Registration Board and deferred for opinion of legal affairs.

Now the firm has informed that description of the dosage form was changed Ribunal syrup to Ribunal Suspension vide DRAP letter No. 15-4/2017-Reg.V (M-267) dated 05.04.2017. Hence w.r.t aforesaid approval the renewal application submitted 15.06.2021 can be considered for the year 2022. Details are as under.

Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Remarks
078904	Ribunal Suspension Each 5ml contains: Ibuprofen… 100mg (B.P Specifications)	26/02/2015 Change of description of dosage form: **15.06.2017**	15.09.2021 Rs. 30000/-	

Decision: **Keeping in view the post registration variation as recorded above, the renewal application dated 15.09.2021 is considered for the year 2022. Hence Registration Board granted renewal to Ribunal Suspension (078904) w.e.f 15.06.2022 to 14.06.2027.**

Item No. II: Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A.	Imported Human Biologicals from Reference Countries	12
B.	Imported Human Biologicals from Non-Reference Countries	4
C.	Local Human Biologicals	31
D.	Imported Veterinary Biologicals from Reference Countries	6
E.	Imported Veterinary Biologicals from Non-Reference Countries	6
F.	Miscellaneous/ Deferred Cases	71
G.	Additional Agenda	3
Total		160

Sr. No.	Assistant Director	Designated No.
1.	Mr. M. Kashif	Deputy Director
2.	Mr. Hafiz Ahsan	AD-I
3.	Mr. Saadat Ali Khan	AD-II
4.	Ms. Haleema Sharif	AD-III

Cases of AD-II (Mr. Saadat Ali Khan)

A: Imported Human Biological product from Reference countries/WHO PQ:

1.	**Name, address of Applicant / Importer** Details of Drug Sale License of importer	M/s Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector No. 22, Korangi Industrial Area, Karachi-74900, Pakistan **License No**: 542 **Address**: Plot No.23 Sec:22 K.I.A Karachi. **Validity**: 25-09-2023 **Status**: License to sell, stock & exhibit for sale, distribute and sell drugs by way of whole sale by of manufacturer, importer or indenter.
	Name and address of marketing authorization holder/Product License Holder (abroad)	M/s Sanofi Healthcare India Private Limited, Survey No. 274, Athvelli Village, Medchal Mendal-501 401, Medchal-Malkajgiri District, Telangana, India
	Name, address of manufacturer(s)	M/s Sanofi Healthcare India Private Limited, Survey No. 274, Athvelli Village, Medchal Mendal-501 401, Medchal-Malkajgiri District, Telangana, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	The Firm has submitted • Legalized copy of CoPP (No. 2284325/TS/2021) issued on 15-12-2021 valid upto 20-11-2024 issued by Drug Control Administration, Government of Telangana for ShanIPV (Inactivated Poliomyelitis Vaccine B.P), Suspension for Injection. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: Once in a year) • Legalized copy of GMP (L. Dis. No. 70967/TS/2021) dated 22/11/2021 valid upto 20/11/2024 issued by Drugs Control Administration, Government of Telangana.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of Power of Attorney dated 28-04-2022 from M/s Sanofi Healthcare India Private Limited. According to the letter, Sanofi Healthcare India Private Limited appoints "M/s sanofi-aventis Pakistan limited" with address "Plot No.23 Sector 22, Korangi Industrial Area, Karachi – 74900, Pakistan" it's truthful attorney for sole purpose of registration of the said product to allow the marketing and distribution within the country of Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

For imported products, specify one the these	☐ Domestic and Export sales ☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	
Details of fee submitted	Rs. 75,000/- via e-deposit slip No. **31729956923** dated 24-05-2022 and differential fee of Rs. 75,000/- via e-deposit slip No. **44680420713** dated 24-10-2022
The proposed proprietary name / brand name	**ShanIPV**, Inactivated Poliomyelitis Vaccine B.P, Suspension for Injection in Multidose Vial – **For Tender Purpose only**
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**One dose of 0.5 mL contains:** **Poliovirus (inactivated)** **Type 1 (Mahoney strain)#……..40 DU**[*+] **Type 2 (MEF-1 strain)#……8 DU**[*+] **Type 3 (Saukett strain) #…….32 DU**[*+] [#]produced on VERO cells [*]DU: D-antigen Unit [+]or equivalent antigenic quantity determined by a suitable immunochemical method.
Dosage form of applied drug	Suspension for Injection
Pharmacotherapeutic Group of (API)	Poliomyelitis Vaccine
Finished product specifications	B.P Specifications – BP monograph submitted by firm
Proposed Pack size	5.0 mL – 10 Doses / Vial (30 x 5.0mL – 300 Doses)
Proposed unit price	**MRP not applicable (For Tender purpose only)**
Shelf Life	36 months
Storage Conditions	2°C to 8°C
The status in reference regulatory authorities	**WHO Prequalified** – Firm submitted the prequalification letter dated 22-Apr-2022
For generic drugs (me-too status)	**Imovax** Polio Vaccine
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO Format. Firm has summarized information related to nomenclature, structure, general properties, manufacture, characterization, control of the API, Justification of specifications, Reference standard or materials, Container Closure System, Stability of drug substance. The firm has also summarized information of drug product including description and composition, pharmaceutical development, manufacture, control of excipients, control of Finished Pharmaceutical Porduct, reference standard or materials, container closure system and stability.
Name, address of drug substance manufacturer	Sanofi Pasteur, 1541, Avenue Marcel Mérieux, Marcy L'Etoile, 69280, France
Module-III Drug Substance:	Firm has submitted drug substance related data containing: General Information, Manufacture, Characterization, Control of Drug Substance, Reference Standards or Materials, Container Closure System, Stability

Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 10 batches. Stability study performed under normal storage conditions on three industrial batches stored in glass bottles at +5˚C ± 3˚C for 36 months and a complementary batch was added in order to check the pH fluctuations observed in two of the three industrial batches. Stability study performed under normal storage conditions on three industrial batches stored in stainless steel tanks at +5˚C ± 3˚C for 24 months. Stability study performed under accelerated storage conditions on three industrial batches stored in stainless steel tanks at +25˚C ± 2˚C for 3 months.
Module-III Drug Product	Firm has submitted drug product related date including Description and Composition, Pharmaceutical Development, Manufacture, Control of Excipients, Control of Drug Product, Reference Standard or Materials, Container Closure System and Stability.
Analytical method validation/verification of product	Firm has submitted analytical procedures along with validation via 3.2.P.5.2 and 3.2.P.5.3
Container closure system of the drug product	The final formulated ShanIPV is filled aspetically in USP Type I glass containers (vials). The filled vials are stoppered with chlorobutyl rubber stoppers and sealed with aluminium and Poly propylene flip top seals.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability studies performed on ShanIPV (filled product) for real time storage conditions +5˚C ± 3˚C for 42 months, accelerated condition 25˚C ± 2˚C for 6 months.
Module-IV	Only toxicology studies are performed as per following details: Two repeat-dose toxicity studies in 12 weeks (once a week) mice and 8 weeks (every 5 days) dogs assessing systemic toxicity - An hypersensitivity test in guinea pigs
Module-V	The firm has submitted summary of nine trials which included more than 1300 Indian subjects (1325 infants) have demonstrated the excellent immunogenicity profile of the vaccines.
Remarks	**Decision: Keeping in view legalized CoPP and WHO Prequalification (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.** **The Board further advised for comments of Costing & Pricing Division regarding the issuance of registration letter for tender purpose only without fixation of MRP.**
2. Name, address of Applicant / Importer	**M/s Novartis Pharma (Pakistan) Ltd., 15, West Wharf, Dockyard Road, Karachi.**
Details of Drug Sale License of importer	License No: 007 Address: 15 West Wharf, Dockyard Road, Karachi, Pakistan. **Address of Godown:** C-21, SITE, Karachi. Validity: 12-03-2023.

	Status: License to sell drugs by way of wholesale
Name and address of marketing authorization holder (abroad)	M/s Sandoz GmbH, Biochemiestr. 10, 6250 Kundl, Austria.
Name, address of manufacturer(s)	M/s Lek Pharmaceuticals d.d, Verovskova 57, 1526 Ljubljana, Slovenia.
Name of exporting country	European Union
Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original & legalized CoPP certificate (No. 20/20/150517) dated 21.10.2020 issued by European Medicine Agency (EMA) for Rixathon 100mg Concentrate for Solution for Infusion. The CoPP confirms product is on market in exporting country. The CoPP also confirms the GMP compliance status of manufacturer.
Details of letter of authorization / sole agency agreement	Firm has submitted product specific Original & Legalized Power of Attorney from Member of Management Board of M/s Lek Pharmaceuticals d.d. Accordingly to the letter, M/s Lek Pharmaceuticals authorizes "M/s Novartis Pharma (Pakistan) Limited" to register product in Pakistan. The letter was issued on 27-10-2020 and valid till 30-10-2023.
Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)/ Biosimilar
Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Dy. No: 32102 Date of submission: 23-11-2021
Details of fee submitted	PKR 150,000/-: 18-11-2021
The proposed proprietary name / brand name	Rixathon 100mg
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml vial contains: Rituximab.....100mg
Dosage form of applied drug	Concentrate for Solution for Infusion
Pharmacotherapeutic Group of (API)	Antineoplastic agent/Monoclonal Antibody
Reference to Finished product specifications	Manufacturer's Specifications
Proposed Pack size	10ml vial – Pack of 2 or 3 vials
Proposed unit price	Proposed MRP per pack shall be furnished later
Shelf Life	3 Years
Storage Conditions	2°C-8°C

The status in reference regulatory authorities	Product is itself approved by EMA.
For generic drugs (me-too status)	Rituxim by M/S Pharmevo (Pvt.) Ltd. (Reg. # 107878) Mabthera by M/S Roche Pakistan Ltd. (Reg. # 031394) Tuximab by M/S Searle Company Ltd. (Reg. # 107882)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO-QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	Rituximab: M/S Sandoz GmbH, Schaftenau Biochemiestrasse 10, 6336 Langkampfen, Austria.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API on accelerated conditions conducted on 5 ± 3°C for 12 months duration and long term conditions I conducted on ≤ -60°C and long term condition II conducted on -40 ± 10°C for 36 months duration.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	Clear, colourless vials made of tubular glass and closed with rubber stoppers. The rubber stoppers are made of chorobutyl rubber. The vial-stopper combination is crimped with an aluminum cap with a flip-off component
Stability study data of drug product, shelf life and storage conditions.	Firm has submitted the long term stability study data at 5 ± 3°C for the duration of 36 months for 02 batches. The accelerated stability study is conducted at 25 ± 2°C / 60 ± 5 % RH for the duration of 6 months for 02 batches.
Module – IV Non-Clinical	Summarized in Biosimilarity data.
Module-V Clinical	Summarized in Biosimilarity data.

Decision: Keeping in view legalized CoPP, approval of European Medicine Agency (EMA) (Reference Regulatory Authority) and biosimilarity data submitted in light of decision of 297th meeting of Registration Board; Registration Board approved the products subject to compliance of current Import Policy for finished drugs.

3.	**Name, address of Applicant / Importer**	**M/s Novartis Pharma (Pakistan) Ltd., 15, West Wharf, Dockyard Road, Karachi.**
	Details of Drug Sale License of importer	License No: 007 Address: 15 West Wharf, Dockyard Road, Karachi, Pakistan. Address of Godown: C-21, SITE, Karachi. Validity: 12-03-2023. Status: License to sell drugs by way of wholesale
	Name and address of marketing authorization holder (abroad)	M/s Sandoz GmbH, Biochemiestr. 10, 6250 Kundl, Austria.
	Name, address of manufacturer(s)	M/s Lek Pharmaceuticals d.d, Verovskova 57, 1526 Ljubljana, Slovenia.
	Name of exporting country	European Union
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original & legalized CoPP certificate (No. 20/20/150517) dated 21.10.2020 issued by European Medicine Agency (EMA) for Rixathon 100mg Concentrate for Solution for Infusion. The CoPP confirms product is on market in exporting country. The CoPP also confirms the GMP compliance status of manufacturer.
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific Original & Legalized Power of Attorney from Member of Management Board of M/s Lek Pharmaceuticals d.d. Accordingly to the letter, M/s Lek Pharmaceuticals authorizes "M/s Novartis Pharma (Pakistan) Limited" to register product in Pakistan. The letter was issued on 27-10-2020 and valid till 30-10-2023.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)/ Biosimilar
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No: 32103 Date of submission: 23-11-2021
	Details of fee submitted	PKR 150,000/-: 18-11-2021
	The proposed proprietary name / brand name	Rixathon 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 50ml vial contains: Rituximab.....500mg

Dosage form of applied drug	Concentrate for solution for infusion
Pharmacotherapeutic Group of (API)	Antineoplastic agent/Monoclonal Antibody
Reference to Finished product specifications	Manufacturer's Specifications
Proposed Pack size	50ml vial – Pack of 1 or 2 vials
Proposed unit price	Proposed MRP per pack shall be furnished later
Shelf Life	3 Years
Storage Conditions	2°C-8°C
The status in reference regulatory authorities	Product is itself approved by EMA.
For generic drugs (me-too status)	Rituxim by M/S Pharmevo (Pvt.) Ltd. (Reg. # 107878) Mabthera by M/S Roche Pakistan Ltd. (Reg. # 031394) Tuximab by M/S Searle Company Ltd. (Reg. # 107882)
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO-QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Name, address of drug substance manufacturer	Rituximab: M/S Sandoz GmbH, Schaftenau Biochemiestrasse 10, 6336 Langkampfen, Austria.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API on accelerated conditions conducted on 5 ± 3°C for 12 months duration and long term conditions I conducted on ≤ -60°C and long term condition II conducted on -40 ± 10°C for 36 months duration.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
Container closure system of the drug product	Clear, colourless vials made of tubular glass and closed with rubber stoppers. The rubber stoppers are made of chorobutyl rubber. The vial-stopper combination is crimped with an aluminum cap with a flip-off component

Stability study data of drug product, shelf life and storage conditions.	Firm has submitted the long term stability study data at 5 ± 3°C for the duration of 36 months for 03 batches. The accelerated stability study is conducted at 25 ± 2°C / 60 ± 5 % RH for the duration of 6 months for 03 batches. Proposed shelf life of finished product is 36 months.
Module – IV Non-Clinical	Summarized in Biosimilarity data.
Module-V Clinical	Summarized in Biosimilarity data.

Bio similarity data as per WHO guidelines submitted by the firm is as follows:

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison • Physicochemical Characterization	**Molecular mass and primary structure:** rituximab is a 145 kDa monoclonal antibody (mAb) composed of two light chains (213 amino acid) and two heavy chains (451 amino acid), which are N-glycosylated at Asn301. Based on its theoretical sequence, digestion with endoproteinase LysC allowed the generation of peptides covering the majority of the entire primary sequence. Together with the LysC data obtained for all batches it can be stated that the sequence of GP2013 is identical to the originator product and thus identical to the theoretical sequence of rituximab. In addition, mass spectrometry analyses showed that all test items had the expected masses in native and reduced/ alkylated forms. • **N-Glycosylation:** Analyses of oligosaccharides showed that GP2013 had consistent oligosaccharide distribution and expected glycosylation for an antibody produced in CHO (Chinese hamster ovary) cells, showing one single N-glycosylation site at the heavy chains. Approximately 99% of the heavy chains are N-glycosylated at Asn301 and there are no other glycosylation sites detected. • **Charged variants**: Charge heterogeneity was evaluated for all test items by CEX and revealed consistent values for acidic and basic peak variants. **Molecular size variants**: Size heterogeneity was assessed by capillary gel electrophoresis and size exclusion chromatography (SEC). The results show that all variants detected are product related and no differences between test items were detected with the exception of the results obtained with SEC. • **Content:** The content ranges of batches sourced from both regulatory jurisdictions are highly overlapping and do not differ from content values determined for GP2013. Thus, all products show the same content with an expected and justified variability caused by the process.
Biological Activity & Immunochemical properties	• **Functional Characterization of Fc Domain:** **i. Characterization of Complement Dependent Cytotoxicity (CDC) Function:** Rituximab has a number of elements that are known to contribute to its mode of action. After binding of the CD20 antigen on the surface of B cells, the complement system is activated via binding of C1q to the Fc part of the antibody, leading to complement dependent cytotoxicity (CDC).

	ii. Characterization of Complement Dependent Cytotoxicity (CDC) Function: The antibody can interact with FcgammaR positive cells and can thereby induce antibody dependent cellular cytotoxicity (ADCC). Furthermore, binding of rituximab can induce apoptosis of the target cell.
Impurities	Degradation pathways such as **deamidation, oxidation, fragmentation, crosslinking, and isomerization** induced by extreme **pH values, aggregation by mechanical stress or oxidative stress** were addressed. In addition, the forced degradation studies were used to predict GP2013 degradation pathways and to compare them to the originator product.
Stability Studies	The currently available stability data for GP2013 DP batches and originator product batches demonstrated a very low susceptibility of rituximab to degradation at long-term storage condition. No relevant differences could be noted between GP2013 and the originator product when stored either at the long-term or at accelerated conditions. **Storage at the long-term condition (5 ± 3°C):** All batches tested demonstrated a very similar stability behavior; no significant changes were observed for the majority of quality characteristics tested over time. **Storage at the accelerated condition (25 ± 2°C):** the stability behavior of GP2013 and the originator products show highly comparable degradation pathways for all investigated parameters.
Non-clinical Comparison	The biological activity of GP2013 was compared to that of MabThera and Rituxan in a number of *in vitro* pharmacology studies that included binding and the various ascribed rituximab MOAs of B cell depletion. **Primary Pharmacodynamic Studies:** • CD20 target Binding • C1q Binding • FcRs and FcRn Binding • ADCC assay • PDMC and Freshly purified NK Cells mediated ADCC assay • CDC Assay • Apoptosis Assay • Whole blood assay **Pharmacokinetic/Toxicokinetic Studies:** • Single-dose PK/PD study in monkey (cyomolgus) male between drug product and originator product • Repeat-dose toxicity study with TK evaluations in monkey (cyomolgus) male & female between drug product and originator product.
Clinical Comparison	Clinical Comparability between GP2013 and the Originator Product: • a pivotal clinical PK/PD, safety, efficacy and immunogenicity study in patients with active Rheumatoid Arthritis (study GP13-201, Part I) and • a pivotal clinical efficacy, PK/PD, safety and immunogenicity in patients with advanced Follicular Lymphoma (study GP13-301). • An open label, single arm, multi-center study to assess the safety and pharmacokinetics of GP2013 monotherapy administered weekly in Japanese patients with CD20 positive low tumor burden indolent B-cell non-Hodgkin's lymphoma. • A randomized, double-blind, controlled study to evaluate PK, PD, safety and efficacy of GP2013 and rituximab in patients with rheumatoid arthritis refractory

or intolerant to standard DMARDs and one or up to three anti-TNF therapies.

Remarks of Evaluator: The fee has been submitted in the Pharmaceutical Evaluation & Registration division' head instead of BE&R division. And now the firm has submitted letter issued by Budget & Account (B&A) division DRAP wherein it has been stated "you are advised to submit the original challans along with an undertaking that the recipts will not be used for more than one application, in the concerned division". The firm has also submitted undertaking on the stamp paper of Rs. 100/- wherein it is mentioned that the recipts will not be used for more than one application.

Decision: Keeping in view legalized CoPP, approval of European Medicine Agency (EMA) (Reference Regulatory Authority) and biosimilarity data submitted in light of decision of 297th meeting of Registration Board, Registration Board approved the products subject to compliance of current Import Policy for finished drugs.

B: Imported Human Biological Product from Non-Reference Countries:

4.	**Name, address of Applicant / Importer**	**M/s SIND MEDICAL STORES,** 13-B, Block 6, PECHS, Karachi.
	Details of Drug Sale License of importer	**License No**: 0257 **Address Sector 13B/B-10, Block 6, PECHS, Karachi.** **Validity:** 01-07-2024
	Name and address of marketing authorization holder (abroad)	**M/s SINOVAC BIOTECH CO.LTD** **For bulk**: No. 39, Shangdi Xi Road, Haidian District, Beijing,P.R.China. **For Formulation, Filling & Packaging** : No. 15, Zhi Tong Road, Changping Science Park, Changping District, P.R.China.
	Name, address of manufacturer(s)	**M/s SINOVAC BIOTECH CO.LTD** **For bulk**: No. 39, Shangdi Xi Road, Haidian District, Beijing,P.R.China. **For Formulation, Filling & Packaging** : No. 15, Zhi Tong Road, Changping Science Park, Changping District, P.R.China.
	Name of exporting country	China.
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	Firm has submitted legalized CoPP (No. Beijing 20210308) dated 18-10- 2021 **valid upto 08-06-2022** issued by Beijing Medical Products Administration Beijing China. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: one year)
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific authorization from Director, Exports of **M/s SINOVAC BIOTECH CO.LTD** According to the letter, the firm **M/s SINOVAC BIOTECH CO.LTD.** authorizes "**M/s SIND MEDICAL STORES** for the purpose of registration, import, promotion, marketing, quoting in private & public (Government) tenders and negotiation with Ministry of Health, Pakistan & Hospitals for the product

	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐Buk import and local repackaging ☐Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form 5 F, Dy No. 2816 dated 28-01-2022.
	Details of fee submitted	Fee of Rs: 150,000/- Dated: 12 January, 2022
	The proposed proprietary name / brand name	**Influenza Vaccine** **(Split Virion, Inactivated, Quadrivalent)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each single dose of PFS of 0.5ml contain: 15mcg haemagglutinin per strain. Each single dose of PFS of 0.5ml contain: H1N1 antigen …15mcg haemagglutinin per strain. H3N2 antigen…15mcg haemagglutinin per strain. BV antigen antigen …15mcg haemagglutinin per strain. BY antigen antigen …15mcg haemagglutinin per strain.
	Dosage form of applied	Suspension for injection
	Pharmacotherapeutic Group of (API)	Biological Product / Vaccines
	Reference to Finished product specifications	Chinese Pharmacopoeia European Pharmacopoeia
	Proposed Pack size	1 Dose x 0.5ml PFS (1's & 50's)
	Proposed unit price	Not demanded
	Shelf Life	12 months
	Storage Conditions	2-8 ˚C
	The status in reference regulatory authorities	Influvac Tetra by Abbot Biologicals B.V, The Netherlands
	For generic drugs (me-	Influvac Tetra (Abbot Lab Pakistan)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

	Name, address of drug substance manufacturer	**M/s SINOVAC BIOTECH CO.LTD** **For bulk**: No. 39, Shangdi Xi Road, Haidian District, Beijing,P.R.China. **For Formulation,** Filling & Packaging : No. 15, Zhitong Road, Changping Science Park, Changping District, P.R.China **Exporter:** Sinovac Biotech (Singapore) Pte. Ltd 80 Robinson Road, #02-00, Singapore 068898
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of Multiple batches (9 batches) manufactured in different years with different virus strains have been applied in the long-term stability study at 2-8°C. Three batches for 0,3,6,9 months,three batches for 0,3,6,9,12,18 months) & three batches for 0,6,9,12 months to support the validity of the monovalent pooled harvest for 12 months. And Accelerated stability data at 25°C for six batches (0,1,2,3 months) The testing items include protein content, bacteria endotoxin,
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of
	Analytical method validation/verification of product	Firm has submitted the of analytical method validation.
	Container closure system of the drug product	Assemblages for the pre fillable syringe consist of: • 1 mL glass barrel, • Plunger rod, • Plunger stopper, • Stainless steel needle, • Needle shield
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of Multiple batches (6 batches) manufactured in different years with different virus strains have been applied in the long-term stability study at 2-8°C for 0,3,6,9,12,18 months. Accelerated stability data at 25°C for six batches (0,7,14,21 & 21 days) and at 37°C for six batches (0,1,3 days). The testing items include protein content, bacteria endotoxin, haemagglutinin content and ovalbumin
	Module-IV Non-Clinical	• Single-Dose Toxicity: Acute Toxicity of Intramuscular injection in Mice. • To observe the irritant reaction of quadriceps femoris muscle after injection of the test drug in rabbits, and to indicate the possible irritation at the injection site in the linical application of the drug, to provide reference for the clinical application of the drug

	Module-V Clinical	**An open-label phase I** and **Randomized, double-blind, controlled phase III clinical trial** to evaluate the safety and immunogenicity of Influenza Vaccine (Split Virion), Inactivated, Quadrivalent in healthy subjects aged 3 years old and older. (Subjects : 2380)
	Remarks:	
	Decision: Keeping in view legalized CoPPs indicating products availability in country of origin, Registration Board approved the products subject to compliance of current Import Policy for finished drugs. The Board further advised that the firm shall update strains of Influenza virus each year as per recommendations of WHO for Northern Hemisphere.	
5.	**Name, address of Applicant / Importer**	**RG PHARMACEUTICA (PVT.) LTD.** BF1-01, First Floor. Gate No. 1, Bahria Orchard, Main Raiwind Road, Lahore.
	Details of Drug Sale Licenseof importer	**License No:** **Address: RG PHARMACEUTICA (PVT.) LTD.** BF1-01, First Floor. Gate No. 1, Bahria Orchard, Main Raiwind Road, Lahore. **Address of go-down: 247, Sunder Industrial Estate, Lahore**
	Name and address of marketing authorization holder (abroad)	**Livzon Mabpharm Inc.** No. 38 North Chuangye Road, Jinwan District, Zhuhai City, Guangdong Province,China
	Name, address of manufacturer(s)	**Livzon (Group) Pharmaceutical Factory** No. 38 North Chuangye Road, Jinwan District, Zhuhai City, Guangdong Province,China
	Name of exporting country	**China**
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (No. Guangdong 2022004)issued on 25-03-2022 **By** Medical Products Administration of Guangdong Province The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: Once a year
	Details of letter of authorization / sole agencyagreement	Firm has Submitted the agency agreement Validity of Agency agreement is 5 years and automatically it will renew aftersuccessive term of one year each**.**
	Status of the applicant	☐ Manufacturer ☒ **Importer** ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**

	Intended use of pharmaceutical product	☒ **Domestic sale** ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ **Finished Pharmaceutical product import** ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No 32871Dated 15-12-2021, Dy. No 10726 dated 28-04-2022
	Details of fee submitted	Rs. 150,000/- Dated 21 September, 2022 (in pharmaceutical division) Rs. 150,000/- Dated 03 November, 2022 (in biological division)
	The proposed proprietaryname / brand name	Infertreat
	Strength / concentration ofdrug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 250mcg (6500IU) Vial
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Sex hormones and modulators of the genital system, gonadotropins, ATC code:G03GA08
	Reference to Finished product specifications	Manufacturer Spec
	Proposed Pack size	Pack Size: … 1 vial Per small box 10 small boxes per Middle box
	Proposed unit price	Retail price As per SRO
	Shelf Life	24 Months. **But stability study of 12 months has been submitted.**
	Storage Conditions	Store and transport below 30 °C in the original package
	The status in reference regulatory authorities	Ovidrele 250mcg/Inj, approved by FDA &EMA
	For generic drugs (me-toostatus)	Ovidrele 250mcg/Inj, of Merck (importer)
	Module-II (Quality OverallSummary)	Firm has summarized information related to nomenclature, structure, general properties, manufacture, characterization, control of the API, Justification of specifications, Reference standard or materials, Container Closure System, Stability of drug substance. The firm has also summarized information of drug product including description and composition, pharmaceutical development, manufacture, control of excipients, control of Finished Pharmaceutical Porduct, reference standard or materials, container closure system and stability.

	Name, address of drug substance manufacturer	**Livzon (Group) Pharmaceutical Factory** No. 38 North Chuangye Road, Jinwan District, Zhuhai City, Guangdong Province,China
	Module-III Drug Substance:	Firm has submitted the drug substance's general information, manufacture, characterization, quality control, Reference Standards or Materials, Container Closure System, Stability and Process Validation Report of Drug Substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The firm has submitted date for four batches at -80^{o}C±10^{o}C (real time) for 0,3,6,9,12,18,24 months & at 5^{o}C±3^{o}C (accelerated Stability testing) for 0.1,2,3,6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification ofproduct	Firm has submitted analytical method validation/verification of the product.
	Container closure system ofthe drug product	Primary container of the product is 2ml neutral borosilicate glass tube injection with 13 mm rubber stopper & aluminum-plastic combination cap.
	Stability study data of drugproduct, shelf life and storage conditions	Firm has submitted stability study data of 3 batches as per Zone IVA. The accelerated stability study data is conducted at 40°C ± 2°C/75% ±5% RH for 6 months. The real time/long term stability study data is conducted at 30°C ± 2°C/75% ± 5% RH for 12 months. Details are Submitted.
	Module-IV	The pharmacodynamics and safety pharmacology of LZM003 were studied (mice & cynomolgus monkey). The pharmacokinetic studies of LZM003 included single-dose pharmacokinetics (non-GLP) and multiple-dose pharmacokinetics (GLP) with cynomolgus monkey via subcutaneous injection. Single Dose Toxicity (in mice) , Repeated Dose Toxicity (Cynomolgus Monkey), In vitro hemolysis (in Rabbit) & Systemic Active allergies (in Guinea Pigs)
	Module-V	Firm has submitted Clinical studies, Healthy Subject PK and Initial Tolerability Study Reports, Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication, Individual Patient Listing for phase I, Individual Patient Listing for phase III. Pharmacokinetic comparison study of LZM003 and Ovidrel in Chinese healthy subjects via single subcutaneous injection A multi-center, randomized, double-blind, positive-drug parallel controlled, equivalence study (Ovidrel 250 μ) 200 subjects. A multi-center, randomized, double-blind, positive-drug parallel-controlled clinical trial to evaluate the efficacy and safety of LZM003 in

		Chinese women for controlled ovarian. Subjects: 229
	Remarks:	
	Decision: Keeping in view legalized CoPPs indicating products availability in country of origin, Registration Board approved the products subject to compliance of current Import Policy for finished drugs. Firm will submit real time stability data of 3 commercial batches up to the demanded shelf life before issuance of registration letter.	

Locally Manufactured Human Biological

6.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	M/S Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd. No 399 Libing Road China (Shanghai) and pilot free trade zone (Formulation (**dilution), filling, testing & packing**)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form 5-F Dy. No 2186 Dated 24-01-2022
	Details of fee submitted	Fee Submitted: Rs.30,000/- dated 26-03-2021.
	Brand Name + Dosage Form + Strength	**Momentum** Lyophilized powder for injection with one ampule of one ml WFI
	Composition	Each vial after reconstitution contains 10 mg of etanercept in 1 ml.

Dosage form of applied drug	Lyophilized powder for injection
Pharmacotherapeutic Group of (API)	Act as IMMUNO SUPPRESSANT Tumor necrosis factor receptor fusion protein
Reference to Finished product specifications	As per innovator's specification
Proposed Pack size	1's Vial /As per DPC
Proposed unit price	
Shelf Life	24 Months
Storage Conditions	(2^0C-8^0C)
The status in reference regulatory authorities	"Enbrel" registered product of Immunex Corporation (Amgen) in USA approved by FDA
For generic drugs (me-too status)	Enbrel (062228) Wyeth (Pfizer) Pakistan Momentum in 25mg (091268) Macter International ltd.
Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions at -20 ℃ for 36months. The accelerated stability data is conducted at 30**º**C ± 2 ℃ /60% ± 5%RH for 10 days for accelerated conditions.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
Container closure system of the drug product	Packaging for Etanercept finished products are 3 ml USP type 1 clear glass vials accompanied with 13 mm Single slit siliconized butyl grey rubber stoppers and aluminum flip off seal, along with

	an ampoule of 1 ml WFI (water for injection) for reconstitution of momentum.
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (two pilot scale & one lab scale) at long term conditions at 5±3°C for 06 months. The accelerated stability data is conducted at 25±2°C 60±5%RH for 6 months

Documents required as per 297th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	**Documents submitted by firm**
The firms shall provide legalized GMP certificate (issued by relevant regulatory authority) of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin. Submission of valid GMP is exempted, if valid GMP status is evident from official website of regulatory authority of country of origin.	Legalized copy of GMP in case of its already registered product Momentum 25mg but it has been expired on 29-09-2021. The firm has submitted copy of new GMP along with verification link which was verified on 04th November, 2022. https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9MTQ3MzkmaXRlbUlkPTJjOWJhMzg0NzU5Yzk1NzcwMTc1OWNjMjcxNmMwMjMw
The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority (or its website) as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk.	Legalized CoPP of 25mg was already submitted by the firm in case of its already registered product Momentum 25mg but the CoPP expired on December, 2018. Now the firm has submitted copy of new CoPP which can be verified online on the official website of NMPA china by the given link was verified on 04th November, 2022. https://www.nmpa.gov.cn/datasearch/en/search-info-en.html?nmpa=aWQ9Nzk0MiZpdGVtSWQ9MmM5YmEzODE3OWQwOGY0ZjAxNzlkMGYyZmRhMjAwMzU=
The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the biosimilarity. However, it will not be required	Provided & Evaluated below

if the finished drug product was approved before implementation of biosimilarity in the said country and finished drug product is still freely available and the firm shall provide the safety, efficacy data of finished drug product as per applicable regulatory requirements at that time.	
The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	The firm has submitted that lot release is not required in country of orgin (BulK provided country).
The firm shall provide the 6 months accelerated and real time stability studies for drug substance & drug product manufactured locally.	Provided
The local manufacturer shall manufacture three trial batches (quantity sufficient to meet the complete testing up to the assigned shelf life both for real time and accelerated stability studies) of the finished biological product to finalize the formulation and then perform tests as per following order: i. Latest Pharmacopoeia ii. Innovator Product iii. Reference Biotherapeutic Product iv. In case aforementioned tests are not available then tests as adopted by drug substance manufacturer shall be followed.	Provided results for the following tests with comparative with Enbrel (Wyeth Pakistan Ltd.) : • Identification and purity by SDS-PAGE, • Purity by Gel Filtration Chromatography • Potency (Protein Concentration) by bicinchoninic acid assay (BCA) Method. • Biological Activity by Cytotoxicity Inhibition assay. • Endotoxin Test by Gel Clot Method • Sterility Test by Membrane Filtration Technique The following tests are also performed: Physical appearance (before & after re-constitution), Reconstitution Time, Particulate Matter (After Reconstitution) Moisture Content (by Karl Fischer), PH, Protein content by BCA Method, Specific Bioactivity, lmmuno identification Western Blotting, Molecular weight identification by SOS-PAGE (Reducing, silver Staining), Purity by SOS- PAGE (Reducing, Silver Staining), Purity by Gel Filtration-HP LC, Bacteria Endotoxin, sterility test.
The manufacturer shall perform all tests locally as mentioned on Certificate of analysis of finished product of drug substance supplier in case of non-pharmacopoeial product.	Submitted as mentioned above
The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form	Provided

in any country of the world (if available).	
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	The firm has submitted copy of supply agreement wherein it has been mentioned that any changes in the process shall be communicated to DRAP. However, the name of bulk manufacturer mentioned is "**Shanghai CP** Guojian Pharmaceutical co. ltd. 399 Libing Road, **Zhangjiang Hi-tech Park**, Shanghai P.R. China" while in provided GMP/FSC the name & address of Bulk manufacturer is "**Sunshine** Guojian Pharmaceutical (Shanghai) co. ltd. 399 Libing Road, China (Shanghai) **Pilot Free Trade Zone**, China" **The firm has submitted clarification letter from its manufacturer where it has been mentioned that manufacturer name has been changed & nomenclature of the adrres has been also changed while the site remain the same.**
Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	The firm has provided SOP for Pharmacovigilance Surveillance. The firm has also provided Commitment on on stamp paper mentioning the said statement.
The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Commitment provided on stamp paper by the applicant.
If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Commitment provided on stamp paper by the applicant.
All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Commitment provided on stamp paper by the applicant.

For the already registered drugs for local manufacturing, the current guidelines shall apply at the time of renewal of product.	

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	**Physicochemical Characterization** **<u>Structure Characterization</u>** i) Primary Structure ii) Relative Molecular Weight by Electrophoresis iii) Molecular Weight by SEC-DLS iv) Peptide Mapping BY HPLC v) Peptide Mass Mapping vi) N-terminal Amino Acid Sequence vii) C-terminal Amino Acid Sequence by LC-MS/MS **Secondary Structure** by Far UV CD Spectrum by Near UV CD Spectrum) **Posttranslational Modification** i) N-glycan Analysis ii) Content of Sialic Acid
Biological Activity & Immunochemical properties	Biological activity in vitro for Yisaipu and Enbrel is tested by TNFα neutralization killing test based on L929 cell with the active reference produced. **Receptor Binding Activity** ELISA Test **Affinity Analysis:** Binding of rhTNFR Affinity with antigen TNF- α **Affinity with Fc segment key receptor** Affinity with FcRn receptor Affinity with FcγRIa receptor Affinity with FcγRIIa receptor Affinity with FcγRIIb receptor Affinity with FcγRIIIa receptor Binding activity with complement C1q **Antibody-dependent cell-mediated cytotoxicity (ADCC)** **Complement dependent cytotoxicity (CDC)** **C-terminal lysine charge variants analysis**
Impurities	**Purity** i) SEC-HPLC Purity ii) HIC-HPLC Purity iii) SDS-PAGE Purity iv) Electric Charge Analysis
Stability Studies	Stability studies are provided.
Non-clinical Studies	**Pharmacology** <u>In-vitro Studies</u>: Comparative Primary Pharmacodynamics i. Murine L929 cells

i. In-vitro Studies ii. In-vivo Studies	ii. Biacore T100 **Secondary Pharmacodynamics (In-vivo Studies.)** -Collagen-induced arthritis (CIA)model in mice -Adjuvant-induced arthritis (AA)model in rats -Dalactos amine-induced neutralizing model in mice **Safety Pharmacology** **Pharmacokinetics** Toxicology studies **i) Single Dose Toxicity (Kunming mice)** **ii) Repeated Dose Toxicity (rhesus model)** **iii) Local Tolerance**
Clinical Studies	**Phase I Clinical Study** Compare the pharmacokinetic properties and tolerability of two formulations of Etanercept in Mexican healthy volunteers to establish biocomparability and non-biocomparability between both. **Phase II Clinical Study** i. Observe the safety and efficacy of rhTNFR: Fc (INN: ETANERCEPT) after administration in the patients with moderate or severe active rheumatoid arthritis (RA).' ii. Randomized double blind, placebo parallel control multi-center clinical trial for the efficacy and safety of treating ankylosing spondylitis with Yisaipu **Phase III Clinical Study** An open label, prospective, non-comparative, multicentre study to assess the safety and efficacy of Etanercept for injection 25mg in patients with moderate to severe active rheumatoid arthritis. **Phase IV Clinical Study** A multi-center and open study to evaluate the safety and efficacy of the recombinant human tumor necrosis factor receptor II antibody fusion protein for injection in the treatment of active rheumatoid arthritis (RA).
Remarks	Phase I is submitted comparative while phase-III clinical study is non-comparartive. However, its already registered strength of the same product i.e. Momentum 25mg was approved & registered on the basis of the same data. And M/s Getz Pharma also imported the same molecule from the same manufacturer which was also approved & registered on the basis of the same clinical trial data.
Decision: Keeping in view the data submitted by the firm in light of guidelines of 297th meeting, Registration Board approved the product in combo pack with WFI (1ml).	

C: Miscellaneous/ Deferred Cases

Locally Manufactured Human Biological i.e. Heparin & Enoxaparin Injections applied by M/s Macter International Limited deferred in 320th meeting of Registration Board.

7.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang

	Road, Xiaochi Town, Huangemei County, Hubei Province, China. (Formulation (**dilution), filling, testing & packing**)
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
Dy. No. and date of submission	Form 5 Dy.No.30665 dated 09-11-2021. Fee Submitted: Rs.30,000/- dated 20-10-2021.
Details of fee submitted	Rs: 30,000/- dated: 20-10-2022
Brand Name + Dosage Form + Strength	**Hepanox** Solution for Injection
Composition	One ml of solution for injection contains 5000 IU of heparin sodium. While 1 vial (5 ml) contains 25000 IU of heparin sodium.
Dosage form of applied drug	Injection
Pharmacotherapeutic Group of (API)	Anticoagulants
Reference to Finished product specifications	B.P
Proposed Pack size	1’s, 2’s, 5’s, 10’s & 25’s vialAs per DPC/
Proposed unit price	
Shelf Life	24 Months
Storage Conditions	(Store below 25^0C)
The status in reference regulatory authorities	Heparin Sodium Injection, USP FDA Approved
For generic drugs (me-too status)	Brand Name: Heparin Injection 25000 IU/ 5ml, 1’s Pack Importer Name: M/s Leo/ Zam Zam Pharma
Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures,

	batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions at 25 ℃ RH 60%±10% for 48months. The accelerated stability data is conducted at 40ºC ± 2 ℃ /60% ± 5%RH for 06 months for accelerated conditions.
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
Container closure system of the drug product	USP Type-I glass vial (5mL),13mm slit less butyl grey stopper 133 mm Flip off aluminum caps
Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (two pilot scale & one lab scale) at long term conditions at 25 ℃ RH 60%±10% for 06 months. The accelerated stability data is conducted at 40ºC ± 2 ℃ /75% ± 5%RH for 06 months for accelerated conditions.

Decision of 320th meeting of RB:

"Registration Board referred the case to Licensing Division for confirmation of manufacturing section for production of Heparin Sodium".

The case was processed to Licensing division for the section requirement of local manufacturing non-rDNA Biological Drugs (i.e. Heparin) whether such products can be manufactured in rDNA Biological section as per current rules/regulation/practice of licensing division or not?

The Licensing division has conveyed the following comments:

"the Central Licensing Board approved **Liquid and Lyophilized recombinant DNA Technology** products (Biological) section in its 229th meeting held on 13-06-2021 under Drugs Act 1976 and rule framed thereunder. However, it is pertinent to mention that matter

regarding conditions/requirement for manufacturing and registration of drugs does not come under the purview of Licensing Division, DRAP".

Submitted for consideration of the Board please.
Remarks :

Decision: Registration Board deferred the case for following:

- **Submission of section wise products details of M/s Macter International Limited Karachi**
- **Submission of pharmaceutical equivalence (Quality comparison) of the product.**

8.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Inhixa 0.2ml vial**
	Composition	Each 0.2 ml vial contains Enoxaparin sodium 20 mg.
	Finished product specifications	Ph. Eur.
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strenght & volume.
	Products already registered in Pakistan	Clexane 20mg/0.2ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of Application, Fee submitted	Dy.No.32430 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in 0.2ml vial is not available in reference country.
9.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China

	Brand Name + Dosage Form + Strength	**Inhixa 0.4ml vial**
	Composition	Each 0.4 ml vial contains Enoxaparin sodium 40 mg.
	Finished product specifications	Ph. Eur.
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strenght & volume.
	Products already registered in Pakistan	Clexane 20mg/0.2ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of Application, Fee submitted	Dy.No.32431 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in 0.4ml vial is not available in reference country.
10.	**Name of Manufacturer**	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Inhixa 0.6ml vial**
	Composition	Each 0.6 ml vial contains Enoxaparin sodium 60 mg.
	Finished product specifications	Ph. Eur.
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strenght & volume.
	Products already registered in Pakistan	Clexane 20mg/0.2ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of Application, Fee submitted	Dy.No.32432 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price /	s & 2's vial/As per SRO'1

	Pack size	
	General Documentation	The formulation in 0.6ml vial is not available in reference country.
11.	**Name of Manufacturer**	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Inhixa 0.8ml vial**
	Composition	Each 0.8 ml vial contains Enoxaparin sodium 80 mg.
	Finished product specifications	Ph. Eur.
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strenght & volume.
	Products already registered in Pakistan	Clexane 80mg/0.8ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of Application, Fee submitted	Dy.No.32433 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in 0.8ml vial is not available in reference country.
12.	**Name of Manufacturer**	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Inhixa 1ml vial**
	Composition	Each ml vial contains Enoxaparin sodium 100 mg.
	Finished product	Ph. Eur.

specifications	
Pharmacological Group	Antithrombotic agent
Shelf life	24 Months (Store below 25^0C)
International availability	Levenox the product is available in PFS in the said strenght & volume.
Products already registered in Pakistan	Clexane 100mg/ml but the product is available in PFS
Type of Form	Form 5
Dy. No. Date of Application, Fee submitted	Dy.No.32434 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
Demanded Price / Pack size	s & 2's vial/As per SRO'1
General Documentation	The formulation in One ml vial is not available in reference country.

Data as per guidelines of 289th meeting of Registration Board;

i) For Bulk Concentrate Import, Local formulation Filling:

	Documents Required	Documents submitted by the firm
i.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Copy of GMP No.2020-20 dated 07-09-2020 issued by Hubei Provincial Drug Administration, China. Copy of GMP issued by Mo Industry and trade of the Russian Federation. Manufactuerer and its address: Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
ii.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Not provided.

iii. The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the similar efficacy and safety to innovator product covering following requirements:

a)	The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange	Heparin sodium is dissolved and through salification, esterification, it is converted to heparin benzyl ester, then, Enoxaparin sodium is formed by alkaline degradation. Following a series of purification process (filtration, oxidization, ultrafiltration, membrane filtration, lyophilization,

chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).

b) The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.

c) The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.

d) The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-

grinding and mixing), the final product Enoxaparin sodium is obtained.

The structure & quality of Enoxaparin sodium has been compared with reference standard (Eu) & reference product**:**

a. Elucidation of Structure and other Characteristics:

i. Molecular weight distribution by LC & eighteen-angle laser scattering instrument, Electronic balance.
ii. Quantitative analysis of uronic acid by Microplate reader.
iii. Qualitative analysis of amino sugar by Ion chromatograph, ampere pulsed, electronic balance.
iv. Qualitative analysis of free anions and combined sulfo groups by Ion chromatograph, Electrical conductivity Dectector.
v. Nuclear Magnetic Resonance analysis by NMR analyzer.
vi. Infrared analysis by Fourier transform infrared spectrometer.
vii. Disaccharide composition analysis by HPLC
viii. Reducing end content analysis by HPLC.
ix. Oligosaccharide sequence LC-MS analysis by Superhigh pressure liquid chromatograph-mass spectrometer
x. Fingerprinting analysis with 2D-LC-Q/Tof-MS

a. Equivalence of heparin source material:

Based on USP monograph, the starting material of Enoxaparin sodium is from porcine intestinal mucosa & these are obtained from marketing authorization. CoA of crude Heparin Sodium has been submitted. Equivalence of Heparin degradation by chemical reaction (Benzethonium heparinate, nHeparin benzyl ester)

Invitro Bioequivalence study of Low molecular weight Heparins for comparison of the product on aPTT & FXa activity with that of reference drug by aPTT assay & Anti-FXa assay.

Equivalence in Biological & Biochemical assays: Anti-factor Xa activity & Anti-

	Xa/anti-IIa ratio between the generic LMWHs should be provided.	factor IIa activity by potency test method of USP mpnograph.
	e) The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	Single center, open, randomized, single dose, two cycle, two-sequence & cross pharmacodynamics bioequivalence study aims to pre-estimate the effects of subcutaneous injection of test preparation Enoxaparin Sodium Injection & reference preparation Clexane in Chinese healthy subject under fasting.
iv.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	NA
v.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	24months real time stability study data at 25°C±2°C, 60%RH±5% RH & 6 months accelerated stability study at 40°C±2°C, 75%RH ±5% RH of drug substance from API manufacturer.
vi.	The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.	• Identification by Size-Exclusion Chromatography (GPC) • Anti-Factor Xa Activity Chromogenic assay • Anti-Factor Ila activity Chromogenic assay • Color & clarity of solution • Light Absorption • Sodium by Atomic Absorption Spectrophotometry • Related Substances by HPLC
vii.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months stability data on all the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.	The stability study has been submitted for lowest 20mg, middle 60mg & highest 100mg vial (as per bracketing) 6-months real time stability study data at 25°C±2°C, 60%RH±5% RH & 6 months accelerated stability study at 40°C±2°C, 75%RH ±5% RH.
viii.	The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used: a. SDS-PAGE for individual proteins b. GC-MS for lipid impurities c. Threshold ® Total DNA Assay System for DNA content.	Related Substances by HPLC: Purity of LMW heparins by using Anion Exchange Chromatography based test. Sodium by Atomic Absorption Spectrophotometry
ix.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall	Not submitted

	inform DRAP immediately along with relevant documents.	
x.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Submitted
xi.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Not submitted
xii.	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Not submitted
xiii.	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Not submitted

The case was deferred in 320th meeting of Registration Board & the firm has submitted reply which are tabulated below.

Decision of the Board	Response of the firm	Remarks
i. Evidence of availability of formulations in vials in Reference Regulatory Authorities.	With reference to your letter no. F.No.3-88/2015-DDC (BD) Para wise answers are given below, (i.) We would like to inform you that marketed formulation of our innovator brand i.e. Lovenox is available in vial in USA, see link provided below for the presence of Enoxaparin vial in USA; •https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020164s110lbl.pdf In number of countries Enoxaparin formulation is marketed in vial & ampoule i.e. in china and India. Web link is provided below: •http://www.baiyujituan.com/english.php?m=product&a=show&id=29 •https://integratedlaboratories.in/enoxaparin-injection-40mg-inoxa-40/	The submitted links were accessed **the products have not been found in vial in the applied concentration in the USFDA or any other reference regulatory authority.** Only available in China & India as per the link submitted by the firm.
ii. Valid legalized Free sale certificate/CoPP either from country of origin or by any reference	• The firm ha ssubmitted copy of CoPP issued by China . The firm has submitted that Finished dosage form of our API supplier HUBEI ENORAY	

regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	BIOPHARMACEUTICAL is registered in country of origin (China) where market authorization holder is Tianjin Chase Sun Pharmaceutical Co.Ltd. Evidence of availability in Chinese market is mentioned in below; https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9MTkxMzc5Jml0ZW1JZD1mZjgwODA4MTdjODMxMmM0MDE3YzliYmZjOGRlMDM2MA== • The firm has also submitted that HUBEI ENORAY BIOPHARMACEUTICAL Co .Ltd also exports Enoxaparin API to turkey region where it is registered with brand name AXEPARIN. Copy of Registration letter & GMP certificate of Turkish brand Axeparin is enclosed as hard copy. Copy cwerificate of Turkish company purchasing API from our Chinese source is also submitted.
iii. Agreement with the source manufacturer (bulk concentrate) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	
iv. Referred the case to Licensing Division for confirmation of manufacturing section for production of Heparin Sodium.	**Comments of Licensing division is given on the previous case.**
v. An undertaking that the firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	**Submitted on stamp paper.**
vi. An undertaking that if any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration	**Submitted on stamp paper.**

shall stand cancelled with immediate effect.	
vii. An undertaking that all the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	**Submitted on stamp paper.**

Decision: Registration Board deferred the case for submission of following:

- **Section wise details of products of M/s Macter International Limited Karachi**
- **Submission of compatibility, extractables, leachebles and other relevant studies of rubber stopper with the product.**

Imported Human Biologicals applied by M/s Nees International, Lahore deferred in 296th meeting of Registration Board

The following two products are deferred in the 296th meeting of Registration Board. The details of the products are as under;

13.	**Name of Importer**	**M/s Nees International ,Office No.6, 3rd Floor Al-Hafeez View Sir Syed Road Gulberg-III, Lahore.**
	DSL details	License No. 171-A/GT/11/2017, Valid: 14 June, 2019 Qualified Person: Umair Ikram Dar
	Name of Manufacturer	**Product License Holder & Manufacturer:** Hugel, Inc. Address: 23 Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si Gangwon-do, Republic of Korea
	Brand Name +Dosage Form + Strength	Botulax Inj (100 units/ /vial) Lyophilized powder for injection
	Composition	Each vial (100 units) Contains….Clostridium botulinum toxin type A (CBFC26 strain)-------100 units
	Finished product specifications	BP specification
	Pharmacological Group	Muscle relaxant, peripherally acting agent
	Shelf life	36 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. (R&I) Dated 6th February 2018 Rs. 100,000/-6th February, 2018
	Demanded Price / Pack size	$60+ 10%FOC /100 units Vial
	General documentation	Legalized CoPP No.2017-A1-2061 dated 16-10-2017 Legalized GMP No. 2017-B1-0313 dated 27-06-2017

		Copy of distribution Agreement
14.	**Name of Importer**	**M/s Nees International, Office No.6, 3rd Floor Al-Hafeez View Sir Syed Road Gulberg-III, Lahore.**
	DSL details	License No. 171-A/GT/11/2017, Valid: 14 June, 2019 Qualified Person: Umair Ikram Dar
	Name of Manufacturer	**Product License Holder & Manufacturer:** Hugel, Inc. Address: 23 Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si Gangwon-do, Republic of Korea
	Brand Name +Dosage Form + Strength	Botulaxinj (50 units/ /vial) Lyophilized powder for injection
	Composition	Each vial (50 units) Contains….Clostridium botulinum toxin type A (CBFC26 strain)-------50 units
	Finished product specifications	**BP specification**
	Pharmacological Group	Muscle relaxant, peripherally acting agent
	Shelf life	36 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 5615 (R&I) Dated 11thFebruary 2019 Rs. 100,000/- 7th February, 2019
	Demanded Price / Pack size	$37.5+ 10% FOC/100 units Vial
	General documentation	CoPP No.2017-A1-2062 dated 16th October,2017 Legalized GMP No. 2017-B1-0313 dated 27-06-2017 Copy of distribution Agreement
Decision of 296th meeting of RB: Registration Board deferred and advised applicant to provide data / evidence regarding availability of formulation in any of reference regulatory authorities. Now the firm that their manufacturer "got registration by the name "Letybo" in different countries of Europe. Like UK, Italy, Spain, Netherland, Ireland, Romania etc." The firm has aslo submitted copy of multiple documents for same. The product i.e. Clostridium botulinum toxin type A (Letibotulinumtoxin A) was searched on the websites of the different reference regulatory authprity website & the formulation in 50 IU was found in the official website of Germany i.e. Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) vide below link. https://www.bfarm.de/EN/Medicinal-products/Information-on-medicinal-products/Research-medicinal-products/AMIce/_node.html But the formulation in 100 IU has been found.		
Decision: Registration Board deferred the case for confirmation of the product formulation in other reference regulatory authorities.		

15. LICENSE WITHDRAWAL OF SHAN 5 – SUSPENSION FOR INTRAMUSCULAR INJECTION – 1'S VIAL OF 0.5ML (REG. NO.090315)

The firm M/s Sanofi Aventis Pakistan Limited, Karachi, Pakistan has applied for withdrawal/ de-registration of their product detailed as under:

Product License Holder & Manufacturer:	**Brand Name & Composition**
Shantha Biotechnics Private Limited, Address: Survey No. 274, Athvelli Village, Medchal Mandal-501 401, Ranga Reddy Distt. Talangana, India	Shan 5 Suspension for Intramuscular Injection Each dose of 0.5ml contains: Diphtheria Toxoid: ≥30 IU; Tetanus Toxoid: ≥60 IU; B. pertussis (Whole cell): ≥4 IU; r-DNA Hepatitis-B Surface Antigen: 10 µg; Purified Capsular Polysaccharide of Hib Conjugated to 20-40 microgram of Tetanus Toxoid (Carrier Protein): 10 µg

In this context the firm has informed that the manufacturer M/s Sanofi Healthcare India Private Limited has withdrawn the license of said vaccine. Moreover, it has been stated that the decision is based on commercial reason and is not related to safety, quality or efficacy of the vaccine.

Decision: Registration Board referred the case to the availability committee.

Product Clotless Injection 40 mg Reg No 074149 and Clotless Injection 60mg, Reg No 074150. (Enoxaparin Sodium) of M/s Himont Pharmaceuticals Lahore for issuance show cause Notice for manufacturing the products without Biological section.

M/s Himont Pharmaceuticals Lahore has applied for the release of their imported raw material Enoxaparin Sodium 0.925 Kg , B.No 8ZE201001, Mfg: Oct 6 2020, Exp: Sep 2023 for their registered product Clotless Injection 40 mg Reg No 074149 and Clotless Injection 60mg, Reg No 074150. The remaining shelf life of the material is 35%.

Sr.No.	**Brand Name and Registration No**
1.	Clotless Injection 40 mg Reg No 074149
2.	Clotless Injection 60mg, Reg No 074150.

The case was placed in the 57th meeting of Committee for disposal of import cases of short shelf life drugs. As Enoxaparin is a biological product hence the Licensing Division was asked to verify/confirm if the firm has approved biological section or not.

The licensing division has forwarded the last inspection report conducted for renewal of DML of the firm wherein it is evidenct that the firm do not have separate approved section for biological products. The case was processed to the Chairman RB to issue showcause to the firm and the case was returned back to BE&R Division with advice to place the matter of registration of product ***'Noclot"*** before the forthcoming meeting of Registration Board please. As the Chairman is not authorized in such case for approval of issuance of show cause notice.

Decision: Registration Board advised to issue a show cause notice to M/s Himont Pharmaceuticals Lahore to explain as to why not the registrations Clotless Injection 40 mg Reg. No 074149 and Clotless Injection 60mg, Reg. No 074150 cancelled as the biological section for production of Biological drugs is not available. The Board further advised to ask the firm that if they desire to be heard in person they may inform accordingly

<u>Cases of AD-III (Ms. Haleema Sharif)</u>

Human Biologicals of Local manufacture:

16.	**Name, address of Applicant / Importer**	**M/s Dow Institute of Life sciences, Ojha Campus, Suparco Road, off main University road, Gulza-e-Hijri, Scheme 33, Karachi**
	Details of Drug Sale License of importer	**License No: 000915** **Address:** Ojha Campus, Suparco Road, off main University road, Gulza-e-Hijri, Scheme 33, Karachi **Validity:** **Status:** License to manufacture by way of formulation.
	Name and address of marketing authorization holder (abroad)	Bulk manufacture: M/s. Changchun Zhuoyi Biological Co., Ltd Address: No.2 Yongxin Road, Economic Development Zone, Shuangyang district, Changchun City Jilin Province, China.
	Name, address of manufacturer(s)	(Bulk Import Local Repack) M/s Dow Institute of Life sciences, Ojha Campus, Suparco Road, off main University road, Gulza-e-Hijri, Scheme 33, Karachi
	Name of exporting country	China (bulk import local repack)
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Not provided
	Details of letter of authorization / sole agency agreement	N/A Bulk import local repack
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.24366 (R&I) Dated 22.09.2020
	Details of fee submitted	Rs. 100,000/-
	The proposed proprietary name / brand name	**Dow-RAB Lyophilized Powder for Injection Rabies Vaccine (Vero Cell) for Human Use**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Lyophilized Part:** Each dose of lyophilized vaccine for immunizing dose (0.5ml) contains: Purified, Inactivated Rabies Virus……...2.5IU (Prepared on Vero cells PM strain of Rabies virus)

		Diluent Part: Each ampule contains: Sterile water for injection…. 0.5ml
	Dosage form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Viral Vaccines
	Reference to Finished product specifications	In-House
	Proposed Pack size	USP type I clear transparent glass vial, 1's vial with 0.5ml diluent
	Proposed unit price	As per SRO/DPC
	Shelf Life	24 months
	Storage Conditions	2-8 ^{o}C
	The status in reference regulatory authorities	Firm is requested in shortcoming letter to provide it with applied strain
	For generic drugs (me-too status)	------
	Module-II (Quality Overall Summary)	Firm has submitted QOS. Firm has summarized information related to general properties, manufacturers, description of manufacturing process, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Changchun Zhouyi BiologicalCo., Ltd. No.2 Yongxin Road, Shuangyang economic Development Area, Changchun, Jilin Province, China.
	Module-III Drug Substance:	Firm has submitted drug substance data related to nomenclature, structure, manufacturers, description of manufacturing process, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and real time stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability studies at 2-8^{o}C of three batches of drug substance for six months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Analytical method validation/verification of product	Firm has submitted validation of Analytical methods of Heparin Sodium Assay, benzyl Alcohol determination.
	Container closure system of the drug product	Not provided
	Stability study data of drug product	Not submitted **2.3.P (Drug Product part) of locally manufactured drug product.**
	Module-IV Non-Clinical	The firm has also submitted the non-clinical overviews.
	Module-V Clinical	The firm has also submitted the clinical overviews and summaries.
	Remarks of Evaluator	i. Stability data is only for three months. ii. Applied vaccine strain is CTN 1V as per documents and clarification submitted by the firm and it has not been confirmed from Reference Regulatory Authorities and also from locally registered product and name strain is also not mentioned on CoPP.
	Decesion: Registration Borad advised to seek following information before approval of minutes • **Seek information from CDC, NIH regarding circulating strains of Rabies virus in Pakistan and need of Inactivated Rabies virus CTN 1V strain vaccine in Pakistan** • **Seek information from NIH regarding strain of their registered rabies virus vaccine.** • **Advised Dow Institute to submit 6 months real time and accelerated stability studies for consideration by Registration Board.** **The Board further advised to process case for consideration of registration Board after submission of 6 months stability data.**	

Imported Veterinary Biologicals from Reference Countries:

17.	**Name and address of Importer**	**M/s UM Enterprises,** Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900
	Detail of DSL	**M/s UM Enterprises,** Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi. Valid till: 22-03-2021 to 21-03-2023.
	Name and address of Manufacturer	**Manufacturer of Drug:** Zoetis Inc 2000 Rockford Road Charles City, Iowa 50616-9101, USA
	Name of exporting country	U.S.A
	Brand Name +Dosage Form + Strength	**Poulvac® Bursaplex® 8000**
	Diary No. Date of R& I & fee	Dy. No. 325R&I Dated 22-11-2021 Rs. 150,000 (Slip No. 813367474116)
	Composition	Each dose contains: Infectious Bursal disease virus strain 2512 ≥ 100 EID_{50} at release. Bursal disease antiserum ≥ 24units at release.

	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	36months (2-7^{o}C)
	Document Details	Certificate of licensing and inspection (Certificate No. 21-02670) is submitted by the firm. Letter of authorization dated 21st June 2021 is submitted by the firm.
	Pack size	8000 doses
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	082025 BDA Blen (Bursal disease vaccine, live virus) Each dose contains: Infectious Bursal disease virus, 2512 strain, at least….100EID50 Bursal disease viral antiserum at least……24 Units Gentamicin…….....0.2mcg Stabilizer….....0.0024ml
	Remarks of Evaluator	For clarification regarding difference in address of manufacturer on Form 5A **(Zoetis Inc 2000 Rockford Road Charles City, IOWA 50616-9101 USA)** and on certificate of licensing and inspection **(Zoetis Inc 2000 Rockford Road Charles City, IA 50616-9101 USA)** firm has submitted that the difference is only in IOWA & IA. Actually, IA stands as an abbreviation for IOWA State.
	Decision: Keeping in view the legalized licensing certificate indicating product availability in the country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Imported Veterinary Biologicals from Non-Reference Countries:

18.	**Name and address of Importer**	**M/s Orion Group, Faisalabad,** 97 Commercial Area, Usman Block, Muslim Town No. 1 Sargodha Road, Faisalabad
	Detail of DSL	**M/s Orion Group, Faisalabad,** Address: 97 Commercial Area, Usman Block, Muslim Town No. 1 Sargodha Road, Faisalabad Valid till: 22-Jan-2023
	Name and address of Manufacturer	**Manufacturer of Drug:** M/s. DOLLVET BIYOTTNOLOGI A.S. Address: Kocoren OSB Mahallesi. 106. Cad. No:6 Eyyubiye / SANLIURFA/TURKY Kocoren OSB Mahallesi. 106. Cad. No:6 Eyyubiye / SANLIURFA/TURKY
	Name of exporting country	Republic of Turky.
	Brand Name +Dosage Form + Strength	LSD-NDOLL (solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 31628 R&I Dated 03-11-2022 Rs. 150,000/- (Slip No. 9167231694)

	Composition	**Lyophilized part:** Each 2ml dose contains: Attenuated LSD Neethling strain… at least $10^{3.5}$ $TCID_{50}$. **Diluent:** Sterile buffered physiological saline: Sodium chloride…8.34mg Disodium hydrogen chloride…2.47mg Sodium dihydrogen phosphate dehydrate 2.47mg Distilled water for Injection…2ml
	Pharmacological Group	Biological
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's Specifications
	Shelf Life	24months----(2-8^{o}C)
	Document Details	**Free Sale Certificate:** Manufacturer: M/s. DOLLVET BIYOTTNOLOGI A.S. **GMP Certificate:** Issued to: M/s. DOLLVET BIYOTTNOLOGI A.S.. **Sole Agency Agreement:** Product specific Sole agency agreement dated 15th June, 2021 is submitted by the firm
	Pack size & Price	10doses Vial: Decontrolled 20ml diluent
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	This product is additional pack of already registered LSD-NDOLL (50 doses vial, 100ml diluent)
	Remarks of Evaluator	
	Decision: Keeping in view the legalized FSC certificate indicating product availability in the country of origin and GMP certificate of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
19.	**Name and address of Importer**	**M/s Orion Group, Faisalabad,** 97 Commercial Area, Usman Block, Muslim Town No. 1 Sargodha Road, Faisalabad
	Detail of DSL	**M/s Orion Group, Faisalabad,** Address: 97 Commercial Area, Usman Block, Muslim Town No. 1 Sargodha Road, Faisalabad Valid till: 22-Jan-2023
	Name and address of Manufacturer	**Manufacturer of Drug:** M/s. DOLLVET BIYOTTNOLOGI A.S. Address: Kocoren OSB Mahallesi. 106. Cad. No:6 Eyyubiye / SANLIURFA/TURKY Kocoren OSB Mahallesi. 106. Cad. No:6 Eyyubiye / SANLIURFA/TURKY
	Name of exporting country	Republic of Turky.
	Brand Name +Dosage Form + Strength	LSD-NDOLL (solution for injection)
	Diary No. Date of R& I & fee	Dy. No. 31629 R&I Dated 03-11-2022 Rs. 150,000/- (Slip No. 1291093191)
	Composition	**Lyophilized part:**

		Each 2ml dose contains: Attenuated LSD Neethling strain… at least $10^{3.5}$ $TCID_{50}$. **Diluent:** Sterile buffered physiological saline: Sodium chloride…8.34mg Disodium hydrogen chloride…2.47mg Sodium dihydrogen phosphate dehydrate 2.47mg Distilled water for Injection…2ml
	Pharmacological Group	Biological
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's Specifications
	Shelf Life	24months----(2-8^{o}C)
	Document Details	**Free Sale Certificate:** Manufacturer: M/s. DOLLVET BIYOTTNOLOGI A.S. **GMP Certificate:** Issued to: M/s. DOLLVET BIYOTTNOLOGI A.S.. **Sole Agency Agreement:** Product specific Sole agency agreement dated 15th June, 2021 is submitted by the firm.
	Pack size & Price	25 doses Vial: Decontrolled 50ml diluent
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	This product is additional pack of already registered LSD-NDOLL (50 doses vial, 100ml diluent)
	Remarks of Evaluator	
	Decision: Keeping in view the legalized FSC certificate indicating product availability in the country of origin and GMP certificate of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Case: Imported Veterinary Biological applied by M/s Snam Pharma, Lahore deferred in 316th meeting of Registration Board.

20. Name and address of Importer	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
Detail of DSL	M/s Snam Pharma, Address: 61-Block G, Phase-I, DHA, Lahore Cannt, District Lahore. Valid till: 14 November, 2022.
Name and address of Manufacturer	M/s Sante Animale Lot 157, zone industrielle Sud
Name of exporting country	Morroco
Brand Name +Dosage Form + Strength	Bovivax LSD-N Vaccine (50 doses)
Diary No. Date of R& I & fee	Dy. No. 8315R&I Dated 30-03-2022 Rs. 75,000/- (Slip No. 10439736)
Composition	**Lyophilizate:** Each dose contains: Attenuated live LSD virus, Neethling strain ≥ $10^{3.5}$ $TCID_{50}$ **Solvent:**

	Calcium chloride dihydrate… 0.132mg Disodium phosphate dihydrate…1.441mg Sodium chloride…8mg Potassium chloride….0.2mg Monopotassium phosphate…0.2mg Magnesium chloride….0.1mg Water for Injection …s.q.f…1ml
Pharmacological Group	Vaccine
Type of Form	Form-5A
Finished Product Specification	Manufacturer's specifications
Shelf Life	24months (2^0C-8^0C) Stability studies of three batches at (2^0C-8^0C) for 30months.
Document Details	Copy of FSC for Bovivax LSD -N lyophilizate and copy of FSC for MCI solvent. Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively. For GMP of manufacturer firm has referred to Eudra GMP Certificate No. 118/2020/GMP. Which is verifiable from the site.
Pack size	50 doses 50ml solvent
Reference Regulatory Authority Availability	N/A
Products already registered in Pakistan	Mevac LSD of Bromed
Remarks of Evaluator	In response to this division's letter firm has submitted following: i. Notarized copy of product specific sole agency agreement. ii. Stability studies of diluent for 20ml and 200ml bottles is submitted. For FSC indicating diluent firm has submitted following: a. Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. b. Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. Document still required: i. FSC indicating free sale status of product in country of origin.
Previous Decision (M-317)	*Registration Board deferred the product for submission of valid legalized Free Sale Certificate indicating product availability in country of origin.*
Evaluation by DBER	*Firm has submitted original legalized FSC which does not indicate product availability in country of origin.*
Previous Decision in 321st RB meeting	*Registration Board deferred the case for submission of evidence of approval of applied product in other countries including reference regulatory authorities.*

Evaluation by DBER	*Firm has submitted that Bovivax LSD-N vaccine is registered and exported to in following countries:* *Bulgaria* *Kenya* *Egypt* *UAE* *To support above statement firm has also submitted copies of registration letters of subject product in Bulgaria, Kenya, Egypt and UAE.* *The firm has further submitted that the manufacturer of Bovivax LDS-N vaccine ca also be verified from the site of FAO (Food and Agriculture Organization of United Nations) and shared following link:* *https://www.fao.org/3/cb1892en/cb1892en.pdf*
Decision: Registration Board deferred the case for further deliberation as FAO is not a regulatory organization and asdvised to confirm free sale status in reference / non-reference regulatory authorities.	
21. Name and address of Importer	**M/s Snam Pharma 61-G, Phase-1, Commercial Area, DHA, Lahore**
Detail of DSL	M/s Snam Pharma, Address: 61-Block G, Phase-I, DHA, Lahore Cannt, District Lahore. Valid till: 14 November, 2022.
Name and address of Manufacturer	M/s Sante Animale Lot 157, zone industrielle Sud-Ouest B.P.278- C.P 28 810 Mohammedia-Morocco.
Name of exporting country	Morocco.
Brand Name +Dosage Form + Strength	Bovivax LSD-N Vaccine (10 doses)
Diary No. Date of R& I & fee	Dy. No. 9929R&I Dated 19-04-2022 Rs. 75,000/- (Slip No. 6035676445)
Composition	**Lyophilizate:** Each dose contains: Attenuated live LSD virus, Neethling strain $\geq 10^{3.5}$ $TCID_{50}$ **Solvent:** Calcium chloride dihydrate… 0.132mg Disodium phosphate dihydrate…1.441mg Sodium chloride…8mg Potassium chloride….0.2mg Monopotassium phosphate…0.2mg Magnesium chloride….0.1mg Water for Injection …s.q.f…1ml
Pharmacological Group	Vaccine
Type of Form	Form-5A
Finished Product Specification	Manufacturer's specifications
Shelf Life	24months (2^0C-8^0C) Stability studies of three batches at (2^0C-8^0C) for 30months.
Document Details	Copy of FSC for Bovivax LSD -N lyophilizate and copy of FSC for MCI solvent.

	Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. For GMP of manufacturer firm has referred to Eudra GMP Certificate No. 118/2020/GMP. Which is verifiable from the site.
Pack size	10 doses 20ml solvent
Reference Regulatory Authority Availability	N/A
Products already registered in Pakistan	Mevac LSD of Bromed
Remarks of Evaluator	In response to this division's letter firm has submitted following: i. Notarized copy of product specific sole agency agreement. ii. Stability studies of diluent for 20ml and 200ml bottles is submitted. For FSC indicating diluent firm has submitted following: c. Notarized copy of marketing authorization letter showing sale of Bovivax LSD-N-Lyophilizate vials of 10,25,50 and100 doses of freeze-dried vaccine+ bottle of 20,50,100 and 200ml of MCI Solvent for live vaccines respectively in Morocco. d. Copy of registration license of biological product for Bovivax LSD-N with following pack vial 10 doses+20ml diluent, 25doses+50ml diluent, 50doses+100ml diluent and 100doses+200ml diluent (MCI sterile diluent) in Egypt. Document still required: i. FSC indicating free sale status of product in country of origin.
Previous Decision (M-317)	*Registration Board deferred the product for submission of valid legalized Free Sale Certificate indicating product availability in country of origin.*
Evaluation by DBER	*Firm has submitted original legalized FSC which does not indicate product availability in country of origin.*
Previous Decision in 321st RB meeting	*Registration Board deferred the case for submission of evidence of approval of applied product in other countries including reference regulatory authorities.*
Evaluation by DBER	*Firm has submitted that Bovivax LSD-N vaccine is registered and exported to in following countries:* *Bulgaria* *Kenya* *Egypt* *UAE* *To support above statement firm has also submitted copies of registration letters of subject product in Bulgaria, Kenya, Egypt and UAE.* *The firm has further submitted that the manufacturer of Bovivax LDS-N vaccine ca also be verified from the site of FAO (Food and*

	Agriculture Organization of United Nations) and shared following link: *https://www.fao.org/3/cb1892en/cb1892en.pdf*
Decision: Registration Board deferred the case for further deliberation as FAO is not a regulatory organization and asdvised to confirm free sale status in reference / non-reference regulatory authorities.	

Imported Veterinary Biological applied by M/s Vety Care (Pvt.) Ltd. Islamabad deferred in 316th meeting of Registration Board.

22. Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** **Plot No. 77, Street No.6, I-10/3 Islamabad.**
Detail of DSL	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
Name and address of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands.
Brand Name +Dosage Form + Strength	**Nobivac Tricat Trio** Lyophilisate and solvent for suspension for injection
Composition	After Freeze-drying Each dose contains: Live FCV strain F9……at least 4.6 log10 PFU Live FVR strain G2620A……at least 5.2 log10 PFU Live FPLV strain MW-1……at least 4.3 log10 TCID50 Nobivac Solvent: Each ml contains: Disodium phosphate dihydrate.....0.31mg Potassium dihydrogen Phosphate ….0.21mg Water for injections to 999.16 mg
Finished Product Specification	Innovator Specs
Pharmacological Group	Veterinary Vaccine
Shelf Life	33 months (2-8^{0}C)
International availability	Not Provided.
Products already registered in Pakistan	Not Available as per record.
Type of Form Dy. No. & Date of application, Fee submitted	Form-5A Dy. No. 11336(R&I) Dated 28-03-2018 Rs. 100000/- 28-03-2018
Demanded Price / Pack size	1's Vial Powder 1's Vial Solvent
General documentation	Valid legalized CoPP No. 249028 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands.
Remarks of Evaluator	The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration.

	Real time stability data provided is of 0,9,15,21,27,36 months instead of appropriate time intervals and only titer and residual moisture is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.
Decision of RB in 288th meeting:	*"Registration Board deferred the case for submission of following by the firm:* *a. Approval status of above product registration by reference regulatory authorities.* *b. Complete stability data indicating all the parameters tested in COA."*
Evaluation by DBER	*The firm has now submitted the following:* *a. Copy of modification approval in Nobivac Tricat Trio indicating registration number of said product issued by Ministry of Economic Affairs, Chief Veterinary Officer of The Netherlands, The Hague. However, as per submitted CoPP the product is not registered in country of origin.* *b. As per Intervet the stability data already provided as per European Union Guidelines, and is being accepted all over the world.*
Decision of RB in 292nd meeting:	*Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.*
Evaluation by expert working group on veterinary drugs	*Referred for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Decision of RB in 313th meeting:	*Deferred for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Evaluation of DBE&R	*Expert opinion from Ministry of National Food Security & Research, Islamabad placed in 317th RB meeting:* *Feline (cat)vaccine.* *It is a routine combination, already many companies have this combination, therefore, may be recommended for import.*
Decision of RB in 317th meeting:	As the firm had not submitted valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies till 317th RB meeting so the Registration Board in its 317th decided as under:

	Deferred the product for submission of valid legalized CoPPs indicating products availability in country of origin and European Union Guidelines regarding stability studies.
Evaluation by DBE&R	***Now the firm has submitted following:*** *Original legalized COPP indicating product availability in country of origin, but the word "live" is missing in it however it is live as per information available on following web link* https://db.cbg-meb.nl/marketedauth/v10471-90wr-29012014.pdf *European Union Guidelines regarding stability studies of veterinary vaccine wherein time interval for stability studies is 0,3,6, 9… months but stability studies of applied formulation* are at *0,9,15,21,27,36 months' time intervals.*
Decision: Deferred for submission of complete stability data indicating all parameters tested in COA and on all time points as recommended by European Union Guidelines.	
23. Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** **Plot No. 77, Street No.6, I-10/3 Islamabad.**
Detail of DSL	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
Name and address of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands
Brand Name +Dosage Form + Strength	**Innovax ND-IBD**
Composition	Each dose(ml) contains: Live Herpesvirus of turkey strain HPV 360*….at least $10^{3.3}$PFU** * HPV 360 is a HVT-based recombinant encoding the NDV F protein and the IBDV VP2
Finished Product Specification	Innovator Specs
Pharmacological Group	Veterinary Vaccine
Shelf Life	36 months (Liquid Nitrogen)
International availability	Not Provided.
Products already registered in Pakistan	Not Available as per record.
Type of Form Dy. No. & Date of application, Fee submitted	Form-5A Dy. No. 11337(R&I) Dated 28-03-2018 Rs. 100000/- 28-03-2018
Demanded Price / Pack size	1's Vial (2000 doses)
General documentation	Valid legalized CoPP No. 249030 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands.
Remarks of Evaluator	The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration.

	Real time stability data provided is of 0, 6, 12, 18, 24, 30, 36, 39 months instead of appropriate time intervals and only titer is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.
Decision of RB in 288th meeting:	"Registration Board deferred the case for submission of following by the firm: a. Approval status of above product registration by reference regulatory authorities. b. Complete stability data indicating all the parameters tested in COA."
Evaluation by DBER	The firm has now submitted the following: a. Copy of market authorization approval of product issued by Icelandic Medicine Agency. b. As per Intervet the stability data already provided as per European Union Guidelines, and is being accepted all over the world.
Decision of RB in 292nd meeting:	Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.
Evaluation by expert working group on veterinary drugs	Referred the case for expert opinion from Ministry of National Food Security & Research, Islamabad.
Decision of RB in 313th meeting	Deferred for expert opinion from Ministry of National Food Security & Research, Islamabad.
Evaluation by DBER	Expert opinion from Ministry of National Food Security & Research, Islamabad placed in 317th RB meeting: This is vector vaccine for gumboro(IBD) already 2 similar vaccines are available in Pakistan. May be recommended for import for making healthy competition.
Decision of RB in 317th meeting	*As the firm had not submitted valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies till 317th RB meeting so the Registration Board in its 317thmeeting decided as under:* ***Deferred the product for submission of valid legalized CoPPs indicating products availability in country of origin and European Union Guidelines regarding stability studies.***
Evaluation by DBER	***Now the firm has submitted following:*** *Original legalized COPP indicating product availability in country of origin (firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP).*

	European Union Guidelines regarding stability studies of veterinary vaccine wherein time interval for stability studies is 0,3,6, 9… months but stability studies of applied formulation are at *0, 6, 12, 18, 24, 30, 36, 39 months' time intervals*
Decision: Deferred for the following: • **For submission of complete stability data indicating all the parameters tested in COA and on all time points as recommended by European Union Guidelines.** • **For clarification regarding status of product would it be in combo pack or otherwise as firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP.**	
24. Name and address of Importer	**M/s Vety Care (Pvt.) Ltd.** **Plot No. 77, Street No.6, I-10/3 Islamabad.**
Detail of DSL	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
Name and address of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands
Brand Name +Dosage Form + Strength	**Nobilis IB Primo QX** Lyophilisate for suspension for spray
Composition	Each dose of reconstituted vaccine contains: Live attenuated avian infectious bronchitis virus, strain D388…$10^{4.0}$-$10^{5.5}$ EID50* *50% egg infective dose
Finished Product Specification	Innovator Specs
Pharmacological Group	Veterinary Vaccine
Shelf Life	15 months (2^0C-8^0C)
International availability	Not Provided.
Products already registered in Pakistan	Not Available as per record.
Type of Form Dy. No. & Date of application, Fee submitted	Form-5A Dy. No. 5721(R&I) Dated 16-02-2018 Rs. 100000/- 16-02-2018
Demanded Price / Pack size	10Cups x 10000 doses
General documentation	Valid legalized CoPP No. 01/17/113770 dated 13-10-2017 issued by EMA indicating product availability in exporting region.
Remarks of Evaluator	Real time stability data provided is of 0, 6, 11, 18 months instead of appropriate time intervals and only **titer and residual humidity** are tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies:

	Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate
Decision of RB in 288th meeting:	*"Registration Board deferred the case for submission of complete stability data indicating all the parameters tested in COA.*
Evaluation by DBER	The firm has now submitted that as per Intervet the stability data already provided as per European Union Guidelines and is being accepted all over the world.
Decision of RB in 292nd meeting:	*Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.*
Evaluation by expert working group on veterinary drugs	*Referred the case for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Decision of RB in 313th meeting:	*Deferred for expert opinion from Ministry of National Food Security & Research, Islamabad.*
Evaluation of DBE&R	*Expert opinion from Ministry of National Food Security & Research, Islamabad placed in 317th RB meeting:* *Already D274 strain is present which gives protection against D388 because* *D388 is IB variant equal to QX virus it may be recommended for import but in killed form not in live form.*
Decision of RB in 317th meeting:	As the firm had not submitted valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies till 317th RB meeting so the Registration Board in its 317th decided as under: ***Deferred the product for submission of valid legalized CoPPs indicating products availability in country of origin and European Union Guidelines regarding stability studies.***
Evaluation by DBE&R	***Now the firm has submitted following:*** *Original legalized COPP indicating product availability in country of origin. (firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP).* *European Union Guidelines regarding stability studies of veterinary vaccine wherein time interval for stability studies is 0,3,6, 9… months but stability studies of applied formulation* are at *0, 6, 11, 18 months' time intervals*
Decision: Decision: Deferred for the following: • **For submission of complete stability data indicating all the parameters tested in COA and on all time points as recommended by European Union Guidelines.** • **For clarification regarding status of product would it be in combo pack or otherwise as firm has applied for approval of lyophilized part of product but product is supplied with diluent as per CoPP.**	

25. Application for Registration of Dow ASV 10ml sterile liquid for injection by M/s Dow Institute of Life sciences.

It is submitted that following registration application of M/s. DOW Institute of Life Sciences Karachi has been received as per following details:

Name of product	Name of Importer	Name of manufacturer	Date of R&I
Dow ASV 10ml sterile liquid for injection Each ml of polyvalent equine immunoglobulin neutralizes following: Cobra: 0.6mg Common Krait 0.45mg Russell's viper: 0.6mg Saw-scaled viper: 0.45mg	Local Manufacturing	M/s. Dow Institute of Life Sciences, Karachi, Pakistan	24-Jan-2022

It is pertinent to mention that the application of the firm indicates that M/s. DOW Institute of Life Sciences, Karachi has Drug Manufacturing License by the way of formulation while in instant application the firm is itself manufacturing the following active ingredients:

i. Cobra Anti venom
ii. Common Krait Anti venom
iii. Russell's Viper Anti venom
iv. Saw-Scaled Viper Anti venom

The matter was referred to Licensing Division for guidance whether the M/s Dow university of Health sciences Karachi, can manufacture above mentioned active ingredients for production of Polyvalent Equine Immunoglobulin on their DML or otherwise.

Division of licensing opined as under:

All those manufacturers who are manufacturing Biological products including vaccines and utilizing indigenous source as raw material be advised to get also DML on same premises for Basic manufacture of drugs as GMP of raw materials could be ensured before formulation of product.

The opinion/advice of licensing division has already been communicated to the firm M/s Dow Institute of Life sciences.

Decision: Registration Board deferred the case and advised to submit copy of DML by way of basic manufacturing as per comments of Licensing Division.

Sr. No.	Details of application	No. of Cases
A.	Imported Human Biologicals from Reference Countries	9
B.	Imported Human Biologicals from Non-Reference Countries	2
C.	Local Human Biologicals	28
D.	Imported Veterinary Biologicals from Reference Countries	5
E.	Imported Veterinary Biologicals from Non-Reference Countries	4
F.	Miscellaneous/ Deferred Cases	55
G.	Additional Agenda	3

Total	106

Sr. No.	Assistant Director	Designated No.	No. of Cases
1.	Mr. M. Kashif	DD	43
2.	Mr. Hafiz Ahsan	AD-I	22
3.	Mr. Saadat Ali Khan	AD-II	38
4.	Ms. Haleema Sharif	AD-III	3

Cases of DD (Mr. Muhammad Kashif)

(A) Regularization of renewal of registration with approval of composition as per COPP/FSC, (B) change in name of manufacturing site (Site remains the same) and Marketing Authorization Holder and approval of composition as per COPP/FSC.

(A) M/S Saadat International is required for Regularization of Renewal of their already registration biological product as per following details:

Renewal Status

S.No.	Reg. No	Brand Name	Initial Reg. date	Last Renewal Granted upto	Last Renewal Submission Date	Renewal fee Submitted
26.	019924	Angavac One Dose of vaccine of 0.3 ML Contains: Active substance(s): Inactivated Adenovirus type 4, PAK strain, …… 7.0 $\log_{10}$ $CCID_{50}$* minimum titre before inaction	27-03-2010	25-03-2020	17-04-2020 i.e. 22 days after due date	Rs. 40,000/-
27.	018430	Aviffa RTI One dose contains: Active substance(s) Live attenuated avian rhinotracheitis virus,…….. ≥102.3 CCID50(*) VCO3 strain *CCID50: 50% cell culture infective dose.				Rs. 40,000/-
28.	018496	AVINEW Each dose of reconstituted vaccine contains: Active substance(s): Live Newcastle disease virus, … ≥5.5 log10 EID50(*)				Rs. 40,000/-

		VG/GA-AVINEW STRAIN *EID50: 50% Egg infective dose.				
29.	011480	Bigopest One dose of 0.3ml contains: Active substance(s): Inactivated Gumboro disease virus, VNJO strain ……. ≥5 PD50(*) Inactivated Newcastle disease virus, Ulster strain, …. ≥16 HAI.U (**) or ≥50 PD50(*) Inactivated Infectious Brochitis disease virus, Mass 41 strain, ……. ≥80 HAI.U (**) (*)PD50:qs to obtain one 50% protective dose in the vaccinated animal. (**)HAI.U: qs to obtain a mean haemagglutination inhibiting antibody titre of 1 in the vaccinated animal.				Rs. 40,000/-
30.	006859	Bioral H120 One dose contains: Avian Infectious Bronchitis virus, H120 strain ……. 3.7 – 5.0 log10 EID50(*) (*)EID50: 50% Egg infective dose.				Rs. 40,000/-
31.	013652	BUR 706 Live attenuated avian infectious bursal disease virus, …… ≥4 log10 CCID50(*) S706 strain (*)CCID50: 50% cell culture infective dose.				Rs. 40,000/-
32.	013653	Cor-2 One dose of 0.3ml contains: Variant coronavirus (PL84084 strain), inactivated …… QS. 2.3 SNU(*)				Rs. 40,000/-

		Variant coronavirus (CR88121 strain), inactivated …… QS. 2.3 SNU(*) (*) 1 SNU: qs to obtain vaccinated chickens a mean alpha SN antibodies titre of 1 log10.				
33.	013075	Diftosec CT Lyophilisate Live attenuated fowl pox virus « avian », DCEP 25 stain ……. ≥ 103.0CCID50(*) Excipient QS 1 dose of 0.01ml (*) CCID50: 50% cell culture Infective dose.				Rs. 40,000/-
34.	034559	Gallimune 208 ND+FLU H9 M.E I dose of 0.3 ml contains: Inactivated Avian influenza virus, H9N2 strain, …… ≥ 10 HI. U Inactivated Newcastle disease virus, Ulster 2C strain …… ≥ 16HI.UFr* HI: Haemagglutination inhibiting *:Minimam antibody titre obtained in the animal vaccinated with 1/50 of dose (fractionated dose).				Rs. 40,000/-
35.	049594	Gallimune 302 ND+IB+EDS Inactivated Newcastle disease virus, …… ≥50 PD50 (*) Ulster 2C strain Inactivated Infectious bronchitis virus, ……. ≥18 HI. U (**) Massachusetts 41strain Inactivated egg drop syndrome virus (EDS76), …….. ≥180 HI. U (**) V127 strain Excipient QS of 1 dose of 0.3ml One unit (U) corresponding to an antibody titre of 1.				Rs. 40,000/-

		(*)PD50 : minimum protective dose according to monograph 0870 of Eur.Ph. (*)HI.U: Haemagglutination inhibiting				
36.	057113	Gallimune 407 ND+IB+EDS+ART Each dose of 0.3 mL contains: Inactivated Newcastle disease virus, …… ≥ 50 PD50(*) Ulster 2C strain Inactivated infectious bronchitis virus, ……. ≥ 18HI.U (**) Massachusetts 41 strain Inactivated egg drop syndrome virus EDS76, ……. ≥ 180 HI.U(**) V127 strain Inactivated avian rhinotracheitis virus (swollen head syndrome),…….. ≥ 0.76 ODD(***) VCO3 Strain (growing medium: chicken eggs, vero cells)* Excipient(s) The concentration are expressed by the antibody titre obtained during the potency test. One unit (U) corresponding to an antibody titre of 1. (*) PD50: minimum protective dose according to monograph 0870 of Eur. Ph. (**) HI.U: haemagglutination inhibiting. (***) ODD : optical density difference in.				Rs. 40,000/-
37.	034560	Gallivac IB88 One dose contains: Infectious bronchitis coronavirus attenuated, ……. ≥4.0 log10 EID50(*) CR88121 strain				Rs. 40,000/-

		(*) EID50: 50% Egg infective dose.				
38.	011485	Haemovax One dose of 0.3 ml contains: Haemophilus paragallinarum serotype A, …….. ≥0.6 SIU(*) Haemophilus paragallinarum serotype C, …….. ≥0.6 SIU(*) Excipient(s) (*): 1 SIU: QS to obtain in the vaccinated chicken a seroconversion index of 1 log10				Rs. 40,000/-
39.	018497	Primodog Live attenuated canine parvovirus, C-780916 strain …….. ≥105.5 CCID50* Excipient QS 1 dose of 1 ml *CCID50: cell culture infective dose 50%.				Rs. 40,000/-
40.	006853	Rabisin One dose of 1 mL contains: Inactivated rabies virus G52 strain …….. ≥ 1 IU* Excipient(s) (*) Minimum titres according to the European pharmacopoeia requirements.				Rs. 40,000/-
41.	082024	Avinew Neo 1000DS One dose contains: Live Newcastle disease virus, VG/GA-AVINEW strain……. ≥5.5 log10 EID50(*)	03-11-2016	02-11-2021	22-12-2021 i.e. almost 1 month, 21 days after due date	Rs. 60,000/-

		(*) EID50: 50% Egg infective dose.				

(B). M/s Saadat International applied for the change in name of manufacturing site(Site remains the same) & Marketing Authorization Holder (MAH) of their already registered products as following details:

Sr. No	Reg. No.	Brand Name	Existing Name of Marketing Authorization Holder & Manufacturer	Demanded Name of Marketing Authorization Holder & Manufacturer
42.	019924	Angavac	Product License Holder: M/s Merial 29 Avenue Tony Garnier 69007, Lyon, france Manufacturer: M/s Merial Rue De L'Aviation, 69800 St. Priest, France	Product License Holder: Boehringer Ingelheim Animal Health France 29 Avenue Tony Garnier 69007, Lyon, France. Manufacturer: Boehringer Ingelheim Animal Health France Rue De L'Aviation, 69800 St. Priest, France
43.	018430	Aviffa RTI		
44.	018496	Avinew		
45.	011480	Bigopest		
46.	006859	Bioral H120		
47.	013652	Bur-706		
48.	013653	Cor-2		
49.	013075	Diftosec CT Injection		
50.	034559	Gallimune 208		
51.	049594	Gallimune 302 ND+IB+EDS		
52.	057113	Gallimune 407 ND+IB+EDS+ART		
53.	034560	Gallivac IB88		
54.	011485	Haemovax		
55.	018497	Primodog		
56.	006853	Rabisin		
57.	082024	Avinew NeO 1000ds		

The case has been evaluated as per SOPs in 283rd meeting revised in 292nd meeting of Registration Board and tabulated below:

Documents required as per SOP	Documents submitted by the firm	Remarks
Application on Form-5F	Submitted	
Required fee as per relevant SRO.	Fee Challans Sr. no. 44-59 of Rs. 7,500/- deposited on 21-05-2021 total Rs. 120,000/- the remaining fee of each 142500/- per product is deposited on 07-10-2022 total Rs. 2,280,000/- So total fee Rs. 2,400,000/- is deposited as per the current full fee of Rs. 1,50,000/- per product deposited	

Copy of registration letter and last renewal status	Products. at Sr. No. 44-58 are transferred from the previous registration holder on 27-03-2010, the last renewal was done on 17-04-2020(after due date). Products. at Sr. No. 59 is registered on 03-11-2016, PRV of MAH approval is issued on 12-12-18. last renewal is submitted on 22-12-2021 i.e. almost 1 month, 21 days after due date.	Products. at Sr. No.44-59 require regularization.
Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	Legalized following documents are submitted. Sr. No. 44 Angavac : COO attached FSC is not submitted. Sr. No. 45 Aviffa RTI: FSC attached Sr. No. 46 Avinew: FSC attached Sr. No. 47 Bigopest: FSC attached Sr. No. 48 Bioralh H120: FSC attached Sr. No. 49 Bur :FSC attached Sr. No. 50 Cor-2 : FSC attached Sr. No. 51 Diftosec CT : FSC attached Sr. No. 52 Gallimune 208 ND+Flu H9 M.E: COO is attached Sr. No. 53 Gallimune 302 ND+IB+EDS: FSC attached Sr.No.54 Gallimune 302 ND+IB+EDS+ART: FSC attached Sr. No. 55 Gallivac IB88: FSC attached Sr. No. 56 Haemovax: FSC attached Sr. No. 57 Primodog: FSC attached Sr. No. 58 Rabisin: FSC attached Sr. No. 59 Avinew NeO 1000ds: FSC attached	The firm for the Products at S. No. 44 & 52 COO is submitted without Free sale status.
Site master file of new manufacturing site in case of change of manufacturing site/ source	NA	
Revised Sole Agency Agreement when there is change in MAH	Submitted	
Undertaking that provided information/ documents are true & correct.	Submitted	

Submitted for consideration of the Board;

Decision: The Board decided as under:

a. **Registration Board regularized the registration of products at S. No. 28 to 42 w.e.f. 25-03-2020 to 24-03-2025 and product at S. No. 43 w.e.f 02-11-2021 to 01-11-2026.**
b. **Registration Board approved M/s Boehringer Ingelheim Animal Health France 29 Avenue Tony Garnier 69007, Lyon, France as Product License Holder and M/s**

Boehringer Ingelheim Animal Health France Rue De L'Aviation, 69800 St. Priest, France as Manufacturer for the products at S.No. 45 to 51 & 53 to 59.

c. Registration Board deffered the cases of products at S. No. 44 and 52 for submission of Free sale certificate in country of origin or registration status in Reference Regulatory Authorities.

CASE: M/s Saadat International has applied for (A) Regularization of Renewal of Registration with approval of composition as per COPP/FSC, (B) change of name of the manufacturing site (Manufacturing site remains the same) with updated address and change of Legal entity (Marketing Authorization Holder) and (C) combipack approval.

(A) M/s Saadat International is required for Regularization of Renewal of their already registration biological product as per following details:

S.No.	Reg. No	Brand Name	Initial Reg. date	Last Renewal Granted upto	Last Renewal Submission Date	Renewal fee Submitted
58.	082026	Purevax Feline 4 Feline Rhinotracheitis-Calici-Panleukopenia- Chlamydia psittaci Vaccine, Modified Live Virus and Chlamydia (Freeze-dried pellet) Each dose contains: Feline Rhinotracheitis Virus, F-2 strain at least ……10 $^{4.9}$ $TCID_{50}$ Feline Calicivirus, F-9 strain at least ……..10 $^{4.7}$ $TCID_{50}$ Feline Panleukopenia virus, Johnson leopard origin strain , at least 10 $^{4.0}$ $FAID_{50}$ Chlamydia psittaci, strain 905, at least……..$10^{2.5}$ EID_{50} Sucrose/ gelatin stabilizer ……..25-35% Gentamicin ……≤30 µg/ml	03-11-2016	02-11-2021	18-07-2022 i.e. almost 9 Months after due date	Rs. 300,000/-
59.	082026	Recombitek C6 (Freeze dried live vaccine) Each ml dose of vaccine contains: Canine distemper-Canrypox Vector…… ≥10 6.4TCID50 Canine Adenovirus Type 2 …….. ≥ 10 4.3 TCID50	03-11-2016	02-11-2021	18-07-2022 i.e. almost 9 Months after due date	Rs. 300,000/-

		Canine Parainfluenza ……≥ 10 3.9 TCID50 Canine Parvovirus ……. ≥ 10 3.3 TCID50 Stablizer …… 25-35% Gentamicin …….. ≤ 30µg/ml				

(B) Change of name of the manufacturing site (Manufacturing site remains the same) with updated address and change of Legal entity (Marketing Authorization Holder).

M/s Saadat International has applied for: **(A)**change of Name of the manufacturing site **(**Manufacturing site remains the same**)** with updated address and change of Legal entity (Marketing Authorization Holder) as per following details:

S. No.	**Reg. No.**	**Brand Name with composition**	**Existing Name of Marketing authorization Holder/ Manufacturer**	Demanded Name of Marketing authorization Holder and Manufacturer with updated address
60.	082022	Purevax Feline 4 Feline Rhinotracheitis-Calici-Panleukopenia- Chlamydia psittaci Vaccine, Modified Live Virus and Chlamydia (Freeze-dried pellet) Each dose contains: Feline Rhinotracheitis Virus, F-2 strain at least ……$10^{4.9}$ $TCID_{50}$ Feline Calicivirus, F-9 strain at least ……..$10^{4.7}$ $TCID_{50}$ Feline Panleukopenia virus, Johnson leopard origin strain , at least $10^{4.0}$ $FAID_{50}$ Chlamydia psittaci, strain 905, at least……..$10^{2.5}$ EID_{50} Sucrose/ gelatin stabilizer ……..25-35% Gentamicin ……≤30 µg/ml	M/s Merial Inc. 115 Transtech Drive Athens, Georgia 30601 USA	**MAH:** M/s Boehringer Ingelheim Animal Health USA Inc., 2621 North Belt Highway St. Joseph, Missouri 64506 USA. **Manufacturer** M/s Boehringer Ingelheim Animal Health USA Inc. 1730 Olympic Drive Athens, Georgia 30601 USA
61.	082026	Recombitek C6 (Freeze dried, live vaccine) (Freeze dried live vaccine) Each ml dose of vaccine contains: Canine distemper-Canrypox Vector…… ≥$10^{6.4}$$TCID_{50}$		

		Canine Adenovirus Type 2 …….. ≥ $10^{4.3}$ $TCID_{50}$ Canine Parainfluenza …….≥ $10^{3.9}$ $TCID_{50}$ Canine Parvovirus …. ≥ $10^{3.3}$ $TCID_{50}$ Stablizer …… 25-35% Gentamicin …… ≤ 30µg/ml		
62.	084586	Recombitek C6(Suspension part, killed vaccine) (Suspension Part) Each ml dose of diluent vaccine contains: Leptospira canicola ……≥ 40 nephelometric units Leptospira icterohaemorrhagiae …… ≥30 nephelometric units Thimerosal..…….. 1:30,000 final Concentration		

The application has been evaluated as per approved SOPs in 283rd and 292nd meeting of Registration Board for extension in shelf life of the registered imported products and tabulated as under;

Requirements as per SOP	**Documents submitted by the firm**	**Remarks**
Application on Form-5A with required fee as per relevant SRO	Application on company letter head with Fee of Rs. 5,000/- each for the products at S. No 35,36 &37 for change of name and MAH change and Fee of Rs. 5,000/- each for the products at S. No 35,36 &37 for change of street address has been submitted.	
Copy of registration letter and last renewal status	Copy of initial Registration letter (03-11-2016) and last renewal application dated 18-07-2022 (**almost 9 months after due date**) for the product at S. No.35 has been submitted. Copy of initial Registration letter (03-11-2016) and last renewal application dated 18-07-2022 **(almost 9 months after due date)** for the product at S. No.36 has been submitted. Copy of initial Registration letter (25-04-2018) for the product at S. No.37 has been submitted.	Regularization of registration is required for the products at S. No. 35 & 36
Original and Legalized Certificate of Pharmaceutical Product as per WHO format for new MAH name	Original and Legalized CLI for the products at S. No 35,36 &37 has been submitted.	

	Link of manufacturer for both the addresses has been provided from which on google map it has been verified that site is same and only entrance gates are changed from 115 Transtech Drive Athens, Georgia 30601 USA to 1730 Olympic Drive Athens, Georgia 30601 USA.
Revised Sole Agency Agreement when there is change in MAH	Submitted
Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/new name), where the manufacturer and product license holder are different entities	Not applicable
Undertaking that provided information/documents are true & correct.	Submitted

M/s Merial had only two following sites of manufacturing in USA which had been acquired by M/s Boehringer Ingelheim Animal health USA Inc:

1. M/s Merial .1730 Olympic Drive Athens, Georgia 30601 USA.
2. M/s Merial 1168 airport parkway, SW, Gainesville, GA, GA 30501-6816.

Which are changed to:

1. M/s Boehringer Ingelheim Animal Health USA Inc.1730 Olympic Drive Athens, Georgia 30601 USA.
2. M/s Boehringer Ingelheim Animal Health USA Inc. 1168 airport parkway, SW, Gainesville, GA, GA 30501-6816.

In view of above, copy of picture of aerial view of the manufacturing site of submitted by the firm and confirmation on google map on the links provided by the firm it shows that the site is same and only entrance gates are changed for which the firm has no regulatory approval however for both the addresses the firm has submitted Certificates of licensing inspection.

(C) Approval of combo pack for the products at S.No.35 as per following details.

Reg, No.	Brand Name with composition	Packing

082022	Purevax Feline 4 Feline Rhinotracheitis-Calici-Panleukopenia-Chlamydia psittaci Vaccine, Modified Live Virus and Chlamydia (Freeze-dried pellet) Each dose contains: Feline Rhinotracheitis Virus, F-2 strain at least ……10 4.9 TCID50 Feline Calicivirus, F-9 strain at least ……..10 4.7 TCID50 Feline Panleukopenia virus, Johnson leopard origin strain , at least 10 4.0 FAID50 Chlamydia psittaci, strain 905, at least……..102.5 EID50 Sucrose/ gelatin stabilizer ……..25-35% Gentamicin ……≤30 µg/ml Sterile Diluent Sterile water ……1ml vial	One dose vial x 25's 25 x 1-ml vials of Sterile water

Submitted for consideration of the Board;

Decision: Registration Board decided as under:

a. **Regularized the registration of the products at S. No. 60 and 61 w.e.f. 02-11-2021 to 01-11-2026.**
b. **Approved M/s Boehringer Ingelheim Animal Health USA Inc., 2621 North Belt Highway St. Joseph, Missouri 64506 USA as Marketing Authorization Holder and M/s Boehringer Ingelheim Animal Health USA Inc.1730 Olympic Drive Athens, Georgia 30601 USA as manufacturer for the products at S. No. 62 to 64.**
c. **Approved the combo pack of the products at S.No.62.**

63. Extension in labelling exemption for Cerezyme (Reg. No. 107918).

M/s Sanofi Aventis Pakistan Limited, Karachi has submitted that Cerezyme is indicated for a rare disease called Gaucher disease and required to be imported in a limited quantity. Therefore, it is not possible for manufacturer to follow the Packaging and labeling rules of every country at the time of export plus production, packaging, quality controls of this sterile and temperature sensitive product requires specialized methods and techniques of handling under highly controlled environment. The firm requested to extend the exemption of Urdu Text, Registration number and MRP on packs of Cerezyme.The firm has submitted the following documents:

v. Fee Challan of Rs. 7500/- via e-deposit slip No. **80495466** and differential fee of Rs. 2500/- via e-deposit slip No. **631567805** dated **16- Nov-2022**.
vi. Copy of SOPs for control of local repacking operations.
vii. An undertaking that to print the Registration Number and Maximum Retail Price (MRP) on each pack of above product at their Karachi site bearing DML No. 000007, before releasing the goods into the market.
viii. Copy of Registration letter dated 24-05-2021
ix. Copy of DML
x. Copy of permission of Extension in labeling exemption for Cerezyme (Reg. No. 107918) vide letter No. F.3-5/2014-DD(BD)(V-VI) (M-295) dated 13th July 2021.

In this context, it is stated that the last request of the firm for exemption of labeling text for Cerezyme (Reg. No. 107918) was approved by Registration Board in its 295th meeting for one year from the date of issuance of registration letter. The registration letter was issued on 24-05-2021, hence the permission was valid till 24-05-2022.

Decision: Registration Board decided as follows:

- **Acceded to the request of the firm and extended the permission, for one year from the date of expiry of previous permission i.e. 23-05-2022, to import Cerezyme 400 U(1's, 5's & 25's)(Reg. No. 107918) in Standard Export Packs and to locally print MRP and registration number along with urdu text and other parameters as per Drugs (Labelling & Packing) Rules, 1986 before sale of drug at M/s Sanofi Aventis, Plot 23, sector 22, Korangi Industrial Area, Karachi to comply the requirements as per Drugs (Labelling & Packing) Rules, 1986.**
- **Advised firm to submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.**

64. Information case referred by PRVC of biologicals. (Extension of shelf life and approval of combo pack)

M/s Saadat International has applied for Extension of shelf life from 24 months to 36 months of their already registered biological product as per following details:

Reg. No.	Brand Name with composition	Current Shelf Life	Demanded Shelf Life
084586 Dated 25-04-2018	Recombitek C6(Suspension part, killed vaccine) (**Suspension Part**) Each ml dose of diluent vaccine contains: Leptospira canicola ……≥ 40 nephelometric units Leptospira icterohaemorrhagiae …… ≥30 nephelometric units Thimerosal..…….. 1:30,000 final ConcentrationResidual free formaldehyde……≤0.74 g/L	24 months 2-7℃	36 months 2-8℃

The application has been evaluated as per approved SOPs in 283rd and 292nd meeting of Registration Board for extension in shelf life of the registered imported products and tabulated as under;

Requirements as per SOP	Documents submitted by the firm	Remarks
Application with required fee as per relevant SRO.	Application on company letter head with Fee of Rs. 5000/- is submitted	
Copy of registration letter and last renewal status.	Copy of initial Registration letter (25-04-2018) has been submitted.	
Proposed shelf-life, justification & data of long-term stability testing (as per conditions of zone IV-A) including chromatograms for a minimum of 3 commercial scale batches or development scale batches upto the proposed shelf-life.	long-term stability testing +5℃ for three batches of product upto 36 months is submitted.	
Approval of regulatory body of country of origin or Original and legalized Certificate of Pharmaceutical Product as per WHO format.	legalized CLI Product as per WHO format is submitted with the demanded shelf life.	

Undertaking that: Submitted
i. Provided information is true & correct.

As per CLI and registration letters the above product is in combo pack as per following details

Reg, No.	Brand Name with composition
082026	Recombitek C6 **(Freeze dried live vaccine)** Each 1 ml dose of vaccine contains: Canarypox/Canine distempervirus, CP258,Rentschler/onderstepoort strain- …… ≥$10^{6.4}$$TCID_{50}$ Canine Adenovirus Type 2,Toronto A/26/61 strai……. ≥ $10^{4.3}$ $TCID_{50}$ Canine Parainfluenza virus ,D-008 strain…..…≥ $10^{3.9}$ $TCID_{50}$ Canine Parvovirus, 780916 strain ……. ≥ $10^{3.3}$ $TCID_{50}$ Stablizer …… 25-35% Gentamicin …….. ≤ 30µg/ml **(Suspension part, killed vaccine)** Each 1 ml dose of diluent vaccine contains: Leptospira canicola ……≥ 40 nephelometric units Leptospira icterohaemorrhagiae …..… ≥30 nephelometric units Thimerosal..…….. 1:30,000 final Concentration Residual free formaldehyde……≤0.74 g/L

Registration Board in its 307th meeting delegated its power/Functions for Increase/ decrease in shelf life of registered drug to the Chairman Registration Board.

Decision: The PRV Committee for biologicals evaluated the case and Chairman Registration Board, on the recommendations of the committee decided as follows:

a. Approved the combo pack and shelf life of above product on the basis of Certificate of original and legalized Licensing and Inspection issued by United States Department of Agriculture and Animal and Plant Health Inspection Service Veterinary Service as per following details.

" The expiration date of the combination package is the earliest expiration date of the individual product components. The combination package is composed of released product of codes 13D1.R1 and 2671.02.

13D1.R1(Freeze dried live vaccine); the expiration date is 18 months after the initiation of first potency test.

2671.02(Suspension part, killed vaccine): the expiration date is 36 months after the initiation of first potency test.

b. Advised to inform the Registration Board.

Decision: Registration Board acknowledged the informations.

65. Inclusion of parameters in renewal letter

FR is a letter No. NIH-ISB-CBPD/69/Reg/2022 dated Nill from Ghazala Parveen Chief Biological Production division, NIH, Islamabad which states as under:

"This is with reference to DRAP's letter F-9-33/2022 AD(BD)(PRV)(M-318) dated 7th July 2022 on above subject. Please find enclosed herewith the copy for your ready reference at (Flag-A).

The Sera lab is under process of product sample testing for independent product Risk assessment by WHO. In this regard samples along with relevant documentation has to be submitted to NCLB for release at the earliest.

In this regard the essential product information for renewal of registration of drugs under drugs act 1976 and rules framed thereunder is required to be submitted to NCLB on registration renewal letter/certificate.

Registration Number	Product Name /brand name	Specifications	Packing	Storage conditions & shelf life	Maximum retail price.
003846	Polyvalent Snake Antivenom serum (Liquid Equine Immunoglobulins) B.P specifications	Each 1ml of Antivenom neutralizes not less than $2LD_{50}$ challenge venom dose of following snakes: 5.Russell's viper (*Daboia russellii*) 6.Cobra species (*Naja naja,Naja Oxiana*) 7. Common krait (*Bungarus caeruleus*) 8.Saw-scale viper (*Echis carinatus*).	10ml vial	+2 to 8 ℃ 2 years from date of manufacturing.	Current Price Rs.1651.46/- As per SRO.

The above application has been evaluated as per approved SOPs and is tabulated as under;

S. No	Reg. No.	Current parameters	Demanded parameters	Remarks
1.	003846	Polyvalent Anti Snake venom	Polyvalent Snake Antivenom serum (Liquid Equine Immunoglobulins)	Application for change of Brand Name as per Approved SOPs is required to be submitted. The firm has submitted fee of Rs.30,000/-(Full fee for registration for local manufacturing).
2.		Not Mentioned	2 years from date of manufacturing.	Application for change/Inclusion of shelf Life as per Approved SOPs is required to be submitted.
3.		Not Mentioned	(+2 to 8 ℃)	Application for change/Inclusion of labelled storage condition as per Approved SOPs is required to be submitted.
4.		USP Type-I Glass vial of 10ml	10ml vial	
5.		B.P specifications	B.P specifications	Already given.
6.		Not Mentioned	Current Price Rs.1651.46/- As per SRO.	Relates to Pricing Division.

7.	Each 1ml neutralizes: 0.6mg of Russel's viper (Daboia russellii) venom 0.6mg of Black Cobra (Naja naja) venom 0.45mg of saw Scale Viper (Echis carinatus) venom 0.45mg of Common krait (Bungarus caeruleus) venom	Each 1ml of Antivenom neutralizes not less than $2LD_{50}$ challenge venom dose of following snakes: 1.Russell's viper (*Daboia russellii*) 2.Cobra species (*Naja naja,Naja Oxiana*) 3. Common krait (*Bungarus caeruleus*) 4.Saw-scale viper (*Echis carin.atus*).	Registration Board in its 318th approved the expression of titer of current composition from not less than $2LD_{50}$ challenge venom dose.

The firm has submitted following documents:

1. Application.
2. A copy of regularization of registration letter.
3. Fee of Rs. 30,000/- (Full fee for registration for local manufacturing).
4. Justification of change of the expression of titer of current composition to not less than $2LD_{50}$ challenge venom dose.

Registration Board in its 307th meeting delegated its power/Functions for all the parameters except S. No. 6 (Which relates to Pricing Division) and Registration Board has also not specifically delegated its power/Functions change of Expression of Titer at S. No. 7 to the Chairman Registration Board.

Decision: Registration Board decided to approve request as per following details:

Brand Name & Composition	**Other parameters**
Polyvalent Snake Antivenom serum (Liquid Equine Immunoglobulins) Each 1ml of Antivenom neutralizes not less than 2 LD_{50} challenge venom dose of following snakes: Russell's viper (*Daboia russellii*) Cobra species (*Naja naja, Naja Oxiana*) Common krait (*Bungarus caeruleus*) Saw-scale viper (*Echis carinatus*)	**Container closure system: 10 ml vial Specification: British Pharmacopoeia Shelf Life: 2 years Storage conditions: 2°C to 8°C**

66. Constitution of Post Registration Variations Committee (PRVC) of Biologicals.

1st meeting for the Post Registration Variations for Biologicals was held on 15th - 16th November, 2022 in the Office of the Director BE&R, Division DRAP, Drug Regulatory Authority of Pakistan, Islamabad. The meeting was chaired by Dr. Obaidullah, Director(PE&R)/ Chairman Drugs Registration Board DRAP.

Following officers attended the meeting:

1. **Dr. Noor-us-Saba Director(BE&R), DRAP**
2. **Ms. Aisha Irfan Additional Director (BE&R), DRAP**
3. **Mr. Zeeshan Nazir Bajar Additional Director(PE&R), DRAP**
4. **Mr. Muhammad Kashif, Deputy Director(BE&R), DRAP**

Following will be the members of PRVC of biologicals for evaluation and approval of post registration variations of biological products for which the Registration Board has already delegated its functions to the Chairman Registration Board in its various meetings for approval of such cases.

1. **Chairman Registration Board, DRAP**
2. **Director (BE&R), DRAP**
3. **Secretary Registration Board /Additional Director(PE&R), DRAP**
4. **Additional Director (BE&R), DRAP**
5. **Deputy Director (BE&R), DRAP**
6. **Assistant Director (BE&R), DRAP**

Decision: Registration Board constituted the Post Registration Variation Committee for Biologicals and the committee which will comprise of the following members. Furthermore the committee can also co-opt any member if required:

1. **Chairman Registration Board, DRAP**
2. **Director (BE&R), DRAP**
3. **Secretary Registration Board /Additional Director(PE&R), DRAP**
4. **Additional Director (BE&R), DRAP**
5. **Deputy Director / Assistant Director (BE&R), DRAP**

67. Change in expression of titer.

M/s Hilton Pharma (Pvt.) Ltd has applies for change in Expression of Titer of their already registered biological product as per following details.

Reg. No. and date	**Brand Name and Composition**	**Existing Expression of Titer**	**Demanded Expression of Titer**
084989 dated 30-10-2017	Medivac ND G7 Emulsion (Inactivated vaccine) Each dose (0.5ml) of vaccine contains: Inactivated Newcastle disease virus, MD15 strain…at least 50 PD_{50}	Each dose (0.5ml) of vaccine contains: Inactivated Newcastle disease virus, MD15 strain…at least 50 PD_{50}	Each dose (0.5ml) of vaccine contains: Inactivated Newcastle disease virus, MD15 strain ……at least10^7 EID_{50}

There is no approved SOP for change in Expression of Titer and the firm has submitted following documents.

1. Application with fee for the product along with Brand name change fee of Rs.152500/- is submitted.
2. Registration letter dated 30-10-2017 is submitted.
3. Justification for proposed change for the products is submitted.
4. Legalized CoPP issued by the Ministry of Ministry of Agriculture Directorate General Of Livestock and Animal Health Services Indonesia mentioning the demanded expression of titer.

5. Undertaking is submitted that the provided documents are true and correct.

Registration Board has not specifically delegated its power/Functions change of Expression of Titer already registered drugs to the Chairman Registration Board.

Decision: The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee deferred the case for deliberation in Registration Board along with status of innovator and other registered drug products.

Decision: Registration Board deferred the case for provision of any reference product with requisite expression of titer.

68. Change in Expression of Titer

M/s Hilton Pharma (Pvt.) Ltd has applies for change in Expression of Titer of their already registered biological product as per following details.

Reg. No. and date	**Brand Name and Composition**	**Existing Expression of Titer**	**Demanded Expression of Titer**
084988 dated 30-10-2017	Medivac ND Gumboro Emulsion vaccine (Freeze Dried Live Vaccine) Each dose (0.5ml) contains: Inactivated Newcastle Disease Virus, LaSota Strain..at least …….50 PD_{50} Inactivated infectious bursal disease virus, winterfield 2512 strain…at least 800 serum neutralization (SN).	Each dose (0.5ml) contains: - Inactivated Newcastle Disease Virus, LaSota Strain..at least …….50 PD_{50} Inactivated infectious bursal disease virus, winterfield 2512 strain…at least 800 serum neutralization (SN).	Each dose (0.5ml) contains: - Inactivated Newcastle Disease Virus, LaSota Strain..at least …….10^{7} EID_{50} Inactivated infectious bursal disease virus, winterfield 2512 strain…at least $10^{4.5}$ EID_{50}.

There is no approved SOP for change of expression of titer but the firm has submitted following documents.

1. Application with fee of Rs. 10,000/- for the products is submitted.
2. Registration letters for the product dated 30-10-2017 is submitted.
3. Justification for proposed change for the product is submitted.
4. Legalized CoPP issued by the Ministry of Ministry of Agriculture Directorate General of Livestock and Animal Health Services Indonesia mentioning the demanded expression of titer
5. Undertaking is submitted that the provided documents are true and correct.

Registration Board has not specifically delegated its power/Functions change of Expression of Titer already registered drugs to the Chairman Registration Board.

Decision: The Committee evaluated the case and Chairman Registration Board, on the recommendations of the committee referred the case for deliberation in Registration Board along with status of innovator and other registered drug products

Decision: Registration Board deferred the case for provision of any reference product with requisite expression of titer.

Cases of AD-I (Mr. Hafiz Ahsan)

Imported Human Biological product from Reference countries (WHO PQ):

69.	Name, address of Applicant / Importer	**M/s Amson Vaccines & Pharma (Pvt.) Ltd.** Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
	Details of Drug Sale License of importer	License No: DHO-ISB-465 Address: Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad. Validity: 10-07-2024
	Name and address of marketing authorization holder	M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161-Indonesia.
	Name, address of manufacturer(s)	M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161-Indonesia.
	Name of exporting Country	Indonesia
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted original legalized CoPP Certificate (No. RG.01.05.32.321.02.20.1264). The CoPP specifies free sale status of the product in the country of origin along with its availability. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific authorization from Director, Exports of M/s PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161-Indonesia. According to the letter, the firm M/s PT Bio Farma authorizes "M/s Amson Vaccines & Pharma (Pvt.) Ltd. for the purpose of registration, import, promotion, marketing, quoting in private & public (Government) tenders and negotiation with Ministry of Health, Pakistan & Hospitals for the product.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 9056; Dated: 08-04-2022
	Details of fee submitted	Rs: 150,000/-, Dated: 02-02-2022 (Slip No.6343890596)
	The proposed proprietary name / brand name	MEASLES VACCINE FREEZE-DRIED + Diluent (WFI)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.5ml contains Live attenuated Measles Virus (CAM-70 strain less than 1000 $CCID_{50}$/0.5 ml)…….not less than 1000 $CCID_{50}$
	Dosage form of applied	Lyophilized Vaccine for Injection

	Drug	
	Pharma co therapeutic Group of (API)	Measles Vaccine
	Reference to Finished product specifications	WHO Specifications
	Proposed Pack size	**10's Vials (10 doses/Vial) with 10 ampoules of diluent (WFI) of 5 ml each**
	Proposed unit price	As per SRO
	Shelf Life	36 months
	Storage Conditions	2°C -8°C and protected from light
	The status in reference regulatory authorities	WHO PQ Vaccine https://extranet.who.int/pqweb/content/measles-vaccine
	For generic drugs (me-too status)	Measles vaccine live attenuated, (freeze – dried) lyophilized injection. Imported by PEARL & PEARLS INTERNATIONAL Reg. #. 052298
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/S PT Bio Farma (Persero), Jalan Pasteur 28, Bandung 40161- Indonesia
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	All 3 batches of measles bulk (MVB) have completed 2 years of Real-time stability study period. The interim result shows that Measles bulk is stable until 2 years at temperature of ≤ -60 °C. The real-time stability study will be continued until 11 years of the stability period. All 3 batches of measles bulk (MVB) had completed 42 months of stability study period. The accelerated time stability study results show that Measles bulk is stable until 24 months at temperature of -25 °C ~ -20 °C.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Analytical method validation of Product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	10 ml USP Type 1 clear glass blow back vials closed with 20 mm bromo butyl RFS rubber stoppers and sealed with Orange plastic covered flip-off aluminum cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Measles vaccine 10 dose at accelerated and real time conditions. All of 3 batches of measles vaccine 10 dose have completed 3 years of Real time stability study period. All testing parameters still fulfilled the requirements at each testing point. The interim result shows that measles vaccine 10 dose is stable until 3 years at temperature of 2°C - 8°C. The stability study will be continued up to 4 years of storage periods. The Accelerated stability study period at temperature of 25±2 ˚C and 30 days at temperature of 37°C ±1°C. The result shows that measles vaccine 10 dose is stable until 6 months at temperature of 25°C ±2°C and 21 days at temperature of 37±1˚C.
	Module-IV Non-Clinical	The firm has submitted that there is no data regarding the non-clinical study of measles vaccine due to the requirement for pre-clinical trial was not implemented at the time when the product was registered. However, for additional information, the tests on animal are conducted as routine test for product release to ensure the safety of product, such as: 1. Abnormal toxicity study for measles vaccine The results of above tests are mentioned in CoA of finished product enclosed in annex 3.2.P.5.4.
	Module-V Clinical	Firm has submitted following: -A randomized, multicenter, controlled field trial to compare the immunogenicity and reactogenicity of CAM-70BF (Perum Biopharma) with Schwarz vaccine, the standard Indonesian EPI Measles vaccines in infants aged 9-11 months. Subjects : 1061 infants of ages ranging between 9 and 11 months old were recruited as study group)
	Remarks of Evaluator: The product is WHO PQ and its status is checked on 22-11-2022 @ https://extranet.who.int/pqweb/vaccines/prequalified-vaccines. The firm has submitted that there is no data regarding the non-clinical study of measles vaccine due to the requirement for pre-clinical trial was not implemented at the time when the product was registered.	
	Decision: Keeping in view the WHO PQ status and legalized CoPP indicating product availability in the country of origin and GMP status of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
70.	Name, address of Applicant / Importer	**M/s Amson Vaccines & Pharma (Pvt.) Ltd.** Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
	Details of Drug Sale License of importer	License No: DHO-ISB-465

		Address Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad. Validity: 07-10-2024
	Name and address of marketing authorization holder	M/s PT Bio Farma (Persero), Jalan Pasteur 28, Bandung 40161- Indonesia
	Name, address of manufacturer(s)	M/s PT Bio Farma (Persero), Jalan Pasteur 28, Bandung 40161- Indonesia
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original legalized CoPP Certificate (No. RG.01.05.32.321.02.20.1233). The CoPP specifies free sale status of the product in the country of origin along with its availability. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific Sole Agency Certificate from Head of International Marketing and Sales Division of M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia. According to the letter, the firm M/S PT Bio Farma (Persero) "M/s Amson Vaccines & Pharma (Pvt.) Ltd. for the purpose of registration, import, promotion, and marketing of the product.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.: 9057 Dated: 08-04-2022
	Details of fee submitted	Rs: 150,000/-, Dated: 10-03-2022 (Slip No.27976524249)
	The proposed proprietary name / brand name	Bivalent Oral Polio Myelitis Vaccine Types 1 and 3. 10 Dose Vial (1 ml)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose (2 drops = 0.1ml) contains: Polio virus type 3 (Sabin strain) …… not less than 10^5.8$CCID_{50}$ Polio virus type 1 (Sabin strain)……..not less than 10^6.0$CCID_{50}$
	Dosage form of applied drug	Oral Solution
	Pharmacotherapeutic Group of (API)	Polio Vaccine
	Reference to Finished	WHO Specifications

	product specifications	
	Proposed Pack size	Multi dose vial of 1ml contain 10 doses x 10's. with 10 droppers
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	-20 °C
	The status in reference regulatory authorities	WHO PQ Vaccine https://extranet.who.int/pqweb/content/bivalent-oral-poliomyelitis-vaccine-type-13-bopv-13-0
	For generic drugs (me-too status)	Oral Bivalent Types 1 And 3 Poliomyelitis Vaccine Imported by M/s SANOFI-AVENTIS PAKISTAN LIMITED. Karachi Reg. #. 072532
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Monovalent Bulk of Poliomyelitis Type 1and Monovalent Bulk of Poliomyelitis Type 3 at accelerated and real time conditions. The real time stability data of Monovalent Bulk of Poliomyelitis Type 1 is conducted at ≤ -60 ºC for 20 years for 3 batches and the real time stability data of Monovalent Bulk of Poliomyelitis Type 3 is conducted at ≤ -60 ºC for 20 years for 3 batches. The Accelerated stability data is conducted at -25 – -20 ºC for 3 years for 3 batches of Monovalent Bulk of Poliomyelitis Type 1 and Type 3.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	2 ml USP Type II clear glass blow back vials closed with bromo butyl RFS rubber stoppers and sealed with 20 mm flip off seals –Identical color
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted Real time stability study data: All 3 batches of Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 10 doses have completed 3 years of stability study period. The result shows that Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 10 doses is stable until 2.5 years at temperature of -25 °C ~ -20°C. The accelerated stability study data: All 3 batches of Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 10 doses have completed the stability study period. The result shows that Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 10 dosess is stable until 7 months at temperature of 5°C ± 3°C, 8 days at temperature of 23°C ± 2°C, and 12 hours at temperature of 37°C ± 1°C.
	Module-IV Non-Clinical	The firm has submitted that there is no data regarding the non-clinical study of bOPV types 1 and 3 since there was no requirement for pre-clinical trial at the time when the product was registered. However, we conduct safety test in animal as a routine test for product release which is enclosed in section 3.2.S.4 for the result of safety test.
	Module-V Clinical	Firm has submitted following: - Comparative Evaluation of immunogenicity and Safety of monovalent Oral polio vaccine type I (mOPV1 Bio Farma) with Trivalent OPV (tOPV Bio Farma) in Indonesian Children. - Immunogenicity of bivalent types 1 and 3 oral poliovirus vaccine: a randomized, double blind, controlled trial - Evaluation on immunogenicity and safety profile of Trivalent OPV (tOPV Bio Farma) with Different Batch numbers in Indonesian infants - Immunogenicity and safety profile of primary dose of bivalent OPV (bOPV Bio Farma) given simultaneously with pentabio and inactivated Poliovirus vaccine (IPV) at the 4th visit in Indonesian infants.
	Remarks of Evaluator: The product is WHO PQ and its status is checked on 22-11-2022 @ https://extranet.who.int/pqweb/vaccines/prequalified-vaccines.	
	Decision: Keeping in view the WHO PQ status and legalized CoPP indicating product availability in the country of origin and GMP status of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
71.	**Name, address of Applicant / Importer**	M/s Amson Vaccines & Pharma (Pvt.) Ltd. Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
	Details of Drug Sale License of importer	License No: DHO-ISB-465 **Address** Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.

		Validity: 07-10-2024
	Name and address of marketing authorization holder	M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia
	Name, address of manufacturer(s)	M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Firm has submitted original legalized CoPP Certificate (No. RG.01.05.32.321.02.20.1236). The CoPP specifies free sale status of the product in the country of origin along with its availability. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific Sole Agency Certificate from Head of International Marketing and Sales Division of M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia. According to the letter, the firm M/S PT Bio Farma (Persero) "M/s Amson Vaccines & Pharma (Pvt.) Ltd. for the purpose of registration, import, promotion, and marketing of the product.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy No. 9055; Dated: 08-04-2022
	Details of fee submitted	Rs: 150,000/-; Dated: 29-03-2022 (Slip No.05272831463)
	The proposed proprietary name / brand name	Bivalent Oral Polio Myelitis Vaccine Types 1 and 3. 20 Dose Vial (2 ml)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose (2 drops = 0.1ml) contains: Polio virus type 3 (Sabin Strain) …not less than 10^5.8$CCID_{50}$ Polio virus type 1 (Sabin Strain)…..not less than 10^6.0$CCID_{50}$
	Dosage form of applied drug	Oral Solution
	Pharmacotherapeutic Group of (API)	Polio Vaccine
	Reference to Finished product specifications	WHO Specifications
	Proposed Pack size	**Multi dose vial of 2ml contain 20 doses x 50's. with 50 droppers**

	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	-20 °C
	The status in reference regulatory authorities	WHO PQ Vaccine https://extranet.who.int/pqweb/content/bivalent-oral-poliomyelitis-vaccine-type-13-bopv-13
	For generic drugs (me-too status)	Oral Bivalent Types 1 And 3 Poliomyelitis Vaccine Imported by M/s SANOFI-AVENTIS PAKISTAN LIMITED. Karachi Reg. #. 072532
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/S PT Bio Farma (Persero), Jalan Pasteur 28, Bandung 40161- Indonesia.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Monovalent Bulk of Poliomyelitis Type 1and Monovalent Bulk of Poliomyelitis Type 3 at accelerated and real time conditions. The real time stability data of Monovalent Bulk of Poliomyelitis Type 1 is conducted at ≤ -60 °C for 20 years for 3 batches and the real time stability data of Monovalent Bulk of Poliomyelitis Type 3 is conducted at ≤ -60 °C for 20 years for 3 batches. The Accelerated stability data is conducted at -25 to -20 °C for 3 years for 3 batches of Monovalent Bulk of Poliomyelitis Type 1 and Type 3.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation of Product	Firm has submitted the details of analytical method validation.

	Container closure system of the drug product	5 ml USP Type II clear glass blow back vials closed with bromo butyl RFS rubber stoppers and sealed with 20 mm flip off seals –Identical color
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted Real time stability study data: All 3 batches of Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 20 doses have completed 3 years of stability study period. The result shows that Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 20 doses is stable until 3 years at temperature of -25 ºC ~ -20°C. The accelerated stability study data: All 3 batches of Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 20 doses have completed the stability study period. The result shows that Bivalent Oral Poliomyelitis Types 1 & 3 (bOPV) 20 doses is stable until 7 months at temperature of 5°C ± 3°C, 8 days at temperature of 23°C ± 2°C, and 12 hours at temperature of 37°C ± 1°C.
	Module-IV Non-Clinical	The firm has submitted that there is no data regarding the non-clinical study of bOPV types 1 and 3 since there was no requirement for pre-clinical trial at the time when the product was registered. However we conduct safety test in animal as a routine test for product release which is enclosed in section 3.2.S.4 for the result of safety test.
	Module-V Clinical	Firm has submitted following: - Comparative Evaluation of immunogenicity and Safety of monovalent Oral polio vaccine type I (mOPV1 Bio Farma) with Trivalent OPV (tOPV Bio Farma) in Indonesian Children. - Immunogenicity of bivalent types 1 and 3 oral poliovirus vaccine: a randomized, double blind, controlled trial - Evaluation on immunogenicity and safety profile of Trivalent OPV (tOPV Bio Farma) with Different Batch numbers in Indonesian infants. - Immunogenicity and safety profile of primary dose of bivalent OPV (bOPV Bio Farma) given simultaneously with pentabio and inactivated Poliovirus vaccine (IPV) at the 4th visit in Indonesian infants.
	Remarks of Evaluator: The product is WHO PQ and its status is checked on 22-11-2022 @ https://extranet.who.int/pqweb/vaccines/prequalified-vaccines. The firm has submitted that there is no data regarding the non-clinical study of bOPV types 1 and 3 since there was no requirement for pre-clinical trial at the time when the product was registered.	
	Decision: Keeping in view the WHO PQ status and legalized CoPP indicating product availability in the country of origin and GMP status of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
72.	Name, address of Applicant / Importer	M/s Amson Vaccines & Pharma (Pvt.) Ltd. Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
	Details of Drug Sale License of importer	License No: DHO-ISB-465 **Address** Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.

		Validity: 07-10-2024
	Name and address of marketing authorization holder (abroad)	M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia
	Name, address of manufacturer(s)	Manufacturing Site Address: M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	Firm has submitted original legalized CoPP Certificate (No. RG.01.05.32.321.03.21.2563). The CoPP specifies free sale status of the product in the country of origin. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of product specific Sole Agency Certificate from Head of International Marketing and Sales Division of M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia. According to the letter, the firm M/S PT Bio Farma (Persero) "M/s Amson Vaccines & Pharma (Pvt.) Ltd. for the purpose of registration, import, promotion, and marketing of the product.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 24876; Dated: 02-09-2022
	Details of fee submitted	Rs: 150,000/-: Dated: 14-07-2022 Deposit Slip No.141159897
	The proposed proprietary name / brand name	**DTP Vaccine**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5ml contains: Purified Tetanus Toxoid…….7.50 Lf/0.5ml Purified Diphtheria Toxoid……...20.00 Lf/0.5ml Inactivated B. Pertussis……12 OU/0.5ml
	Dosage form of applied drug	Suspension for Injection
	Pharmacotherapeutic Group of (API)	J07AJ51. Vaccine
	Reference to Finished product specifications	WHO Specifications
	Proposed Pack size	Multi dose vial of 5ml contain 10 doses x 10's.
	Proposed unit price	As per SRO

	Shelf Life	24 months
	Storage Conditions	2°C - 8°C
	The status in reference regulatory authorities	WHO PQ Vaccine https://extranet.who.int/pqweb/content/dtp-vaccine
	For generic drugs (me-too status)	Boostrix Imported by GSK PAKISTAN.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/S PT Bio Farma (Persero) Jalan Pasteur 28, Bandung 40161- Indonesia
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Diphtheria Toxoid Bulk:** • Accelerated Stability Study All 3 batches of purified diphtheria bulk have completed 6 months of stability study period. All testing parameters still fulfilled the requirements at each testing point. It is concluded that purified diphtheria toxoid is stable until 6 months when stored at temperature 25±2°C and 37±1°C. • Real Time Stability Study All 3 batches of purified diphtheria bulk have completed 6 years of stability study period. All testing parameters still fulfilled the requirements at each testing point. It is concluded that purified diphtheria toxoid is stable until6years at temperature 2°C - 8°C. **Tetanus Toxoid Bulk:** AcceleratedStability Study All 3 batches of purified tetanus bulk have completed 6 months of stability study period. All testing parameters still fulfilled the requirements at each testing point. It is concluded that purified tetanus toxoid is stable until 6 months when stored at temperature 25±2°C and 37±1°C. • Real Time Stability Study All 3 batches of purified tetanus bulk have completed 6 years of stability study period. All testing parameters still fulfilled the requirements at each testing point. It is concluded that purified tetanus toxoid is stable until6years at temperature 2°C - 8°C. **Pertussis Bulk:**

		<u>Accelerated Stability Study</u> All 3 batches of pertussis final bulk have completed the accelerated stability study period. All testing parameters still fulfilled the requirements at each testing point. It is concluded that pertussis final bulk is stable until 6 months at temperature 25 ± 2 °C and 2 months at temperature 37±1°C. <u>Real Time Stability Study</u> All 3 batches of pertussis final bulk have completed 3 years of stability study period. All testing parameters still fulfilled the requirements at each testing point. It is concluded that the shelf life of pertussis final bulk is 3 years at temperature 2°C - 8°C.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	5 ml USP Type 1 clear glass blow back vials closed with bromo butyl RFS Rubber stopper 13 mm having Aluminum flip off-cap 13 mm–Yellow color.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted accelerated study of all 3 batches of DTP vaccine 10 doses have completed 3 months of stability study period at temperature of 25°C ±2°C and 4 weeks at temperature of 37°C ±1°C. The result shows that DTP vaccine 10 dose is stable until 3 months at temperature of 25°C ±2°C and 2 weeks at temperature of 37°C ±1°C. Real time stability study data of all 3 batches of DTP vaccine 10 doses have completed 3 years of stability study period.The result shows that DTP vaccine 10 dose is stable until 3 years at temperature of 2°C - 8°C.
	Module-IV Non-Clinical	The firm has submitted that there is no data regarding the non-clinical study of DTP vaccine due to the requirement for pre-clinical trial was not implemented at the time when the product was registered. However, for additional information, the tests on animal are conducted as routine test for product release to ensure the safety of product, such as: 1. Abnormal toxicity study for adsorbed vaccine 2. Mouse weight gain test for pertussis component Furthermore, to ensure the Immunogenicity of the product following tests were performed. Potency of diphtheria Potency of tetanus Potency of pertussis

		The results of above tests are mentioned in CoA of finished product enclosed in annex 3.2.P.5.4.
	Module-V Clinical	**Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication** • DPT Immunization Efficacy in 2 Months Old Infants in Yogyakarta (Diphteria, pertussis, and tetanus). • Immunogenicity and Safety of a Haemophilus Influenzae Type B Conjugate (PRP-T) Vaccine Combined with or Given Concomitantly with a DTP Whole-Cell Combination Vaccine. • Immunogenicity and Safety of DTwP (Bio Farma) Vaccine Combined with Recombinant Hepatitis B 10µg (GCVC) Vaccine in Indonesian Children. **Study Reports of Uncontrolled Clinical Studies** • Immunity and Safety of DPT Vaccine in Infants • Immunogenicity and safety of DTwP Booster in 18-24 months of age children. • Immunogenicity and safety of DTwP (Bio Farma) vaccine, with modified medium for pertussis cultivation.
	Remarks of Evaluator: The product is WHO PQ and its status is checked on 22-11-2022 @ https://extranet.who.int/pqweb/vaccines/prequalified-vaccines. The firm has submitted that there is no data regarding the non-clinical study of DTP vaccine due to the requirement for pre-clinical trial was not implemented at the time when the product was registered. Following tests are	
	Decision: Keeping in view the WHO PQ status and legalized CoPP indicating product availability in the country of origin and GMP status of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Imported Human Biological product from Non-reference countries:

DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2022-2023** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board, please.

73.	Name, address of Applicant / Importer	M/s Getz Pharma (Pvt.) Ltd. Address: Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan.
	Details of Drug Sale License of importer	Getz Pharma (Pvt.) Limited. Address: Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan. License No.: 570 Valid till: 16.08.2024

	Name and addressof marketing authorization holder (abroad)	Name: Shanghai Henlius Biopharmaceutical Co., Ltd. Address: Building 1 (Building D), No.1289 Yishan Road, Xuhui District, Shanghai, China.
	Name, address of manufacturer(s)	Name: Shanghai Henlius Biopharmaceutical Co., Ltd. Address: Building 1 (Building D), No.1289 Yishan Road, Xuhui District, Shanghai, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No.20220086) valid till 13.06.2024 issued by Shanghai Municipal Medical Products Administration for Adalimumab Injection 40mg/0.8ml. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market of exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection.
		DML: Firm has submitted original legalized Drug Manufacturing License (No. H.20160191) issued by Shanghai Medical Products Administration. The certificate is **valid till 31.12.2025.** Further, firm has submitted copy of EUDRA GMP Certificate (No. IWSF.405.36.2020.KK.1 WTC/0606_01_01/68) issued by MOH-Poland. The certificate is **valid till 12.12.2022.**
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from Chief Executive Officer of Shanghai Henlius Biopharmaceutical Co., Ltd. According to the letter, the firm Shanghai Henlius Biopharmaceutical Co., Ltd. authorizes "Getz Pharma (Pvt.) Limited with its place of business at Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan as their business representative with undisputed powers authorized to deal with the product registration of Adalimumab Injection 40mg/0.8ml in vials in Pakistan as per mutually agreed terms and conditions by both companies. The letter is valid till 22.02.2032. Further, firm has submitted sole agency Agreement between Getz Pharma (Pvt.) Limited and Shanghai Henlius Biopharmaceutical Co., Ltd., issued on 22.02.2032 valid for 10 years from date of issue.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No: 25882- dated 13-09-2022
	Details of fee submitted	PKR 150,000/- dated 16-08-2022
	The proposed proprietary name / brand name	**ADALIMAB Solution for Injection 40mg/0.8mL in vial.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.8mL vial contains: Adalimumab……..40mg
	Pharmaceutical form of applied drug	Clear, colorless to pale yellow solution for Subcutaneous Injection
	Pharmacotherapeutic Group of (API)	Tumor Necrosis Factor alpha (TNF-α) inhibitor ATC Code: L04AB04
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	1's in vial
	Proposed unit price	Rs. 150,000/- (1 vial)
	Shelf Life	24 months
	Storage condition	2°C-8°C
	The status in reference regulatory authorities	Humira Solution for Injection 40mg/0.8mL (M/s AbbVie Inc., USA. USFDA Approved).
	For generic drugs (me-too status)	Not Applicable
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Name: Shanghai Henlius Biopharmaceutical Co., Ltd. Address: Building 1 (Building D), No.1289 Yishan Road, Xuhui District, Shanghai, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of bulk drug substance at accelerated and real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% for 6 months, and the real time stability data is conducted at 2°C to 8°C for 12 months. MS201801 MS201802 MS201803
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted bio-similarity studies with innovator product.
	Analytical method validation/verification of product	Firm has submitted summary of analytical method validation of product.
	Container closure system of the drug product	The primary packaging materials of Adalimumab Injection is vial made of middle borosilicate glass tubing, bromobutyl rubber stoppers for injectable drug, caps made of aluminum-plastic combinations for antibiotics.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 2°C-8°C for 36 months. M20180501 M20180502 M20180503
	Module IV	Detailed in Biosimilarity data mentioned below.
	Module V	Detailed in Biosimilarity data mentioned below.

The firm has submitted biosimilarity data as per following details:

WHO Biosimilarity Guidelines	**Data Submitted by M/s Getz Pharma Karachi**
Quality Comparison Physicochemical Characterization	Adalimumab from Shanghai Henlius has been compared with Humira – Reference Listed Drug (RLD)

Test Category		**Quality Attribute**	**Tier**
Physicochemical characterization	Primary structure	Amino acid sequence	1
		Molecular weight, disulphide linkages, free thiols, posttranslational modifications	2

		Ratio of PTMs	2
	Higher order structure	Higher order structure	2
	Charge Variants and Isoelectric point	Charge variants	2
		Isoelectric point	2
	Glycan	Glycosylation site and modification ratio	2
		Glycan profiling	2
		Sialic acid	2
	Size Variants	High molecular weight species	1
		Low molecular weight species and monomer	2
Functional Assays	Immunochemical properties	FcRn	2
		C1q	3
		FcγRIa, FcγRIIa, FcγRIIb/c, FcγRIIIa (F and V) and FcγRIIIb	3
	Bioactivity	Neutralization of soluble TNFα	1
		Soluble TNFα binding	1
		Transmembrane TNFα binding, Anti-apoptosis	3
		ADCC (reporter gene assay)	3
		ADCC (In vivo simulating assay)	3
		ADCC (Clinically representative assay)	3
		CDC	3
		TNFα、LTα induced inhibition of ICAM-1 expression.	3
Process-related impurities		Residual DNA, HCP and Protein A	1
Forced degradation Study		Degradation products and degradation trends	3

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Biological Activity

Biological activity evaluation included 8 assays. The soluble TNFα binding and neutralization of TNFα are the primary MoA, closely related to clinical outcomes, so they were classified as Tier 1; anti-apoptosis, tmTNFα Binding, ADCC, CDC, TNFα induced inhibition of ICAM-1 expression and LTα induced inhibition of ICAM-1 expression are not related to the efficacy of RA, AS and PS indication treatments, so they were classified as Tier 3.

Quality Attribute		Tier	Method	Reason of Tier
Biological Activity	Soluble TNFα Binding	1	ELISA	Primary MoA
	Neutralization	1	Cell-based assay	
	Anti-apoptosis	3	Cell-based assay	Secondary MoA
	tmTNFα Binding	3	Whole cell-based binding	
	ADCC	3	Cell-based assay	
	CDC	3	Cell-based assay	
	TNFα induced inhibition of ICAM-1 expression	3	Cell-based assay	
	LTα induced inhibition of ICAM-1 expression	3	Cell-based assay	

The similarity results of biological activities suggested that HLX03 (Adalimumab of Shanghai Henlius) and Humira have similar biological activities.

Immunochemical properties

As IgG1, Adalimumab have the ability to bind with C1q, FcRn and FcγR. FcRn is expressed in endothelial cells and monocytes, and is involved in recycling of IgG and regulates its serum half-life, but has a relatively low risk to clinical outcomes. FcRn binding was assigned as Tier 2 attribute. Fc-mediated effector functions are less relevant to MoA, and the abilities to bind with C1q and FcγR have the lowest risk to clinical outcomes. C1q and FcγR binding were assigned as Tier 3 attributes.

Quality Attribute		Tier	Method	Reason of Tier
Immunochemical properties	FcRn binding	2	SPR	Impact PK
	C1q binding	3	ELISA	Least relevant to MoA
	FcγRIa binding	3	SPR	
	FcγRIIa binding	3		

	<table><tr><td></td><td>FcγRIIb/c binding</td><td>3</td><td></td><td></td></tr><tr><td></td><td>FcγRIIIa (F) binding</td><td>3</td><td></td><td></td></tr><tr><td></td><td>FcγRIIIa (V) binding</td><td>3</td><td></td><td></td></tr><tr><td></td><td>FcγRIIIb binding</td><td>3</td><td></td><td></td></tr></table> The similarity results of immunochemical properties and their correlation with clinical outcomes suggested that HLX03 (Adalimumab of Shanghai Henlius) and Humira have similar immunochemical properties.
Impurities	The process related impurities to be tested during drug substance batch release are Protein A, Insulin, HCP and DNA.
Non-clinical Comparison **In-vitro Studies** **In-vivo Studies** **Biological / Pharmacodynamic activity** **Non- clinical toxicity as determined in one repeat dose toxicity study**	Characterization of the primary structure, higher order structure, charge heterogeneity and post-translational modification, glycosylation, molecular size heterogeneity, immunological properties, biological activity, as well as forced degradation, suggesting that HLX03 (Adalimumab of Shanghai Henlius) is highly similar to Humira. Primary pharmacodynamics: • A comparative study of the affinity of HLX03 (Adalimumab of Shanghai Henlius) and Humira to TNFα using Surface Plasmon Resonance technique. • Evaluation of the efficacy of HLX03 (Adalimumab of Shanghai Henlius) in preventing arthritic symptoms in the Tg197 transgenic mouse model of arthritis. • To compare the in-vitro activity of HLX03 (Adalimumab of Shanghai Henlius) with that of Adalimumab (reference product) via Neutralization assay. Safety pharmacology: • Toxicity of recombinant Anti-TNFα Human monoclonal antibody injection after repeated subcutaneous injection in Cynomolgus Monkeys with a 4-week recovery period. Pharmacokinetics: • Pharmacokinetics study of recombinant Anti-TNFα Human monoclonal antibody injection (02 batches) after single subcutaneous injection in Cynomolgus Monkeys. • Pharmacokinetics study of recombinant Anti-TNFα Human monoclonal antibody injection and Adalimumab after single subcutaneous injection in Cynomolgus Monkeys. • Pharmacokinetics study of recombinant Anti-TNFα Human monoclonal antibody injection in Cynomolgus Monkeys. Toxicology: • Tissue cross reactivity study of recombinant Anti-TNFα Human monoclonal antibody injection.

	• In-vitro Hemolysis test of recombinant Anti-TNFα Human monoclonal antibody injection with Rabbit Red Blood Cells. • Toxicity studies of recombinant Anti-TNFα Human monoclonal antibody injection after repeated subcutaneous injection in Cynomolgus Monkeys with a 4-week recovery period. • Toxicity studies of recombinant Anti-TNFα Human monoclonal antibody injection after a single subcutaneous injection in Cynomolgus Monkeys.
Clinical Comparison	• A randomized, double blind, parallel controlled phase I clinical study of HLX03 (Adalimumab of Shanghai Henlius) versus Humira in Healthy Chinese Male subjects for comparison in Pharmacokinetics profile, safety, tolerability and immunogenicity. • A phase III, randomized, double blind, multicenter, active-controlled parallel clinical study to investigate the efficacy and safety of recombinant Anti-TNFα fully human monoclonal antibody injection (HLX03: Adalimumab of Shanghai Henlius) versus Adalimumab injection (Humira) in patients with moderate to severe plague psoriasis (N = 216).
Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin and GMP status of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Imported Veterinary Biologicals from Reference Countries:

74.	**Name of Importer**	**M/s Hipra Pakistan (Private) Limited,** 3rd floor, plot no 8, block CCA, Phase 6-C, DHA, Lahore
	DSL details	License to sell drug as distributor No. 05-352-0058-050528D valid till 19-Feb-2024 **Go Down:** 2nd Warehouse on Left side, Street no 5, Gajjumata Nadir Chowk, Hazara Chowk, Industrial Area Ferozpur Road, Distt Lahore.
	Marketing authorization holder	Laboratorios HIPRA, S.A., Avda. la Selva, 135, 17170 Amer (Girona) Spain.
	Name of Manufacturers	Laboratorios HIPRA, S.A., Carretera C-63, Km 48, 300, Poligono Industrial El Rieral, 17170 Amer (Girona), Spain (Responsible for primary packaging). Laboratorios HIPRA, S.A., Avda. la Selva, 135, 17170 Amer (Girona) Spain. (Responsible for batch release in the EU, quality control and Secondary packaging).
	Exporting country	Spain
	Brand Name + Dosage Form + Strength	GUMBOHATCH, Lyophilisate and solvent for suspension for injection 1000 dose
	Dy. No. Date of Application, Fee submitted	Dy. No. 2055: Dated 28-07-2021 Rs.150,000/- Dated 09-07-2021
	Composition	Each dose of reconstituted vaccine contains

	Live attenuated infectious bursal disease virus, strain 1052…….....$10^{1.18}$-$10^{2.80}$ *PU PU: Potency Units* Solvent: Phosphate buffer solution
Pharmacological Group	Live attenuated vaccine against Infectious Bursal Disease
Type of Form	Form 5A
Finished product specifications	As per European Pharmacopoeia
Shelf life	24 Months (Store at 2°C-8°C)
International availability	Lyophilized Gumbohatch and solvent for Injectable Suspension for Chickens by M/s Laboratorios HIPRA, S.A. (AEMPS approved).
Products already registered in Pakistan	GUMBOHATCH 1000 dose
Demanded Price / Pack size	1000 dose Decontrolled for Veterinary products
Stability data of the finished product	Now the firm has submitted stability study data of 3 batches conducted at 2°C - 8°C for 24 months: P.4D62 P.4S19 P.4T71
Document Details	The firm has submitted copy of certificate of veterinary medicinal product (Certificate No. 05/21/160295) issued by European Medicines Agency, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands on 19-07-2021. The certificate confirms fee sale status of the product in the country of origin as well as GMP status of the manufacturer.

Remarks of Evaluator:

Sr. No.	Observations	Response by the firm
1.	Valid copy of drug sale license is required since submitted copy of DSL is expired on 19-02-2022.	The firm has submitted updated copy of DSL (License No. 05-352-0058-050528D) valid till 19-Feb-2024.
2.	Potency units mentioned in applied composition of live IBDV are between $10^{1.48}$-$10^{2.80}$ which are different from that mentioned in CVMP certificate i.e., $10^{1.48}$-$10^{2.63}$. Clarification is required.	During the registration process, we requested a change in the active substance specifications from $10^{1.48}$ - $10^{2.80}$ PU to $10^{1.48}$- $10^{2.63}$ PU in accordance with EMA (European Medicines Agency) indications. The change refers to limits of acceptance of results of the active substance to release a batch. It is a change of internal specifications of the potency control, not a composition change. *Initially, the firm submitted CoPP with potency units $10^{1.48}$- $10^{2.63}$ PU while now the firm has submitted CoPP potency units which are $10^{1.18}$ – $10^{2.80}$.*
3.	Reference to finished product specifications shall be mentioned.	Innovator's specifications
4.	Clarification regarding primary packing material and desired pack size	For the lyophilisate of the vaccine GUMBOHATCH 1,000 doses the

	of applied formulations.	container used consists of 10 ml glass vials. These vials are closed by rubber stoppers and caps. **Desired Pack size** Cardboard box with 10 freeze-dried powder vials containing 1,000 doses.
5.	The submitted real time stability data is only for 9 months. Provide stability study data till claimed shelf life for product at serial No. 1.	Now the firm has submitted stability study data of 3 batches conducted at 2°C - 8°C for 24 months: **P.4D62** **P.4S19** **P.4T71**

Decision: Registration Board deferred the case for submission of revised dossier with requisite fee in line with updated CoPP with composition of $10^{1.18} – 10^{2.80}$ potency units (PU).

75.

Name of Importer	**,M/s Hipra Pakistan (Private) Limited** **3rd floor, plot no 8, block CCA, Phase 6-C, DHA, Lahores**
DSL details	License to sell drug as distributor No. 05-352-0058-.050528D valid till 19-Feb-2024 **Go down: 2nd Warehouse on Left side, Street no 5, Gajjumata Nadir Chowk, Hazara Chowk, Industrial .Area Ferozpur Road, Distt Lahore**
Name of Manufacturer	,Laboratorios HIPRA, S.A Avda. La Selva, 135 .Amer (Girona) Spain 17170
Name of Exporting country	Spain
Brand Name + Dosage Form + Strength	TOXIPRA S-7 Injectable suspension 250ml dose glass vial
Dy. No. Date of Application, Fee submitted	Dy No. 20522 Dated: 28-07-2021 Fee Submitted: Rs. 150,000 /- dated 09-08-2021
Composition	:Composition per (2ml) dose □□toxoid of type B,C and D Clostridium perfingens.....≥ *IU 10 □ toxoid of type B,C and D Clostridium perfingens.....≥ *IU 5 □ toxoid of type B Clostridium novyi.....≥ 3.5 * IU Toxoid □□of Clostridium septicum.....≥ 2.5 IU * Anaculture of Clostridium chauvoei.....100 % ** protection Toxoid of Clostridium sordellii.....100% ** protection International Units (antitoxin per ml of serum)* Protection level in guinea pig**
Pharmacological Group	Inactivated vaccine against Enterotoxaemia Sudden Death, Blackleg and Black Disease
Type of Form	Form 5-A
Finished product specifications	Innovator's specifications

Shelf life	Months (Store at 2°C-8°C.) 24
Pack size and demanded price	ml dose glass vial / Decontrollered 250
International availability	Spain
Products already registered in Pakistan	Clostrivax Toxipra S-7, 100 ml (Reg # 081816)
Stability data of the finished product	The firm has submitted stability study data of TOXIPRA S7 conducted at 2°C-8°C for three batches (Presentation :(250ml 98LR-1 5J33-1 7Z68-1
General Documentation	:The firm has submitted following • Legalized Free sale Certificate of Pharmaceutical Product, Toxipra-S7, (Reg No: 2770 ESP) issued by Agencia Espanola de Medicamentos y productos .sanitarios dated: 21-06-2021 • Legalized GMP certificate No.ES/053HVI/19 dated 16-09-2021. • .Product specific sole agency agreement

:Remarks of evaluator

.The applied vaccine formulation is an additional pack of approved vaccine

Testing time intervals in the submitted stability study data are 0, 9, 12, 18, 24 months .which are not as per ICH guidelines

Decision: Registration Board deferred the case for submission of stability study data .with frequency of testing at the long term storage conditions as per VICH guidelines

Imported Veterinary Biologicals from Non-Reference Countries:

76.	**Name of Importer**	M/s BroMed Animal Health, 246-A, West Wood Colony, Thokar Niaz Baig, District Lahore.
	DSL details	License to sell drugs as a distributor No.05-352-0066-037660D valid till 18-10-2022.
	Marketing authorization holder	M/s Middle East for Veterinary Vaccines (MEVAC), Second Industrial Zone-Extension part No. 21, 22, 24, 25 El Salhya El Gadeda, Elsharkya Governate, Egypt.
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (MEVAC), Second Industrial Zone-Extension part No. 21, 22, 24, 25 El Salhya El Gadeda, Elsharkya Governate, Egypt.
	Name of exporting country	Egypt
	Brand Name +Dosage Form + Strength	MEVAC Lasota + H120
	Diary No. Date of R& I & fee	Dy. No. 33063 (R&I); Dated 06-12-2021 Rs.150,000 (Slip No.80539971653)
	Composition	Lyophilized cake Each dose contains: Live attenuated Newcastle Disease Virus, LaSota strain ..……..…≥ $10^{6.0}EID_{50.}$ Live attenuated Classic Infectious Bronchitis Virus, H120 strain…….. ≥ $10^{3.5}EID_{50.}$
	Pharmacological Group	Live viral veterinary vaccine

Type of Form	Form-5A
Finished Product Specification	Manufacturer's specification
Shelf Life	24 months (2°C-8°C)
Pack size and demanded price	1000 dose vial / Decontrolled
International availability	N/A
Products already registered in Pakistan	BIO-VAC LS-H120 (1000 and 2500 doses) manufactured by FATRO Italy, Local agent is Forward Solutions (Reg # 077560).
Stability data of finished product	The firm has submitted stability study data of 27 months conducted at 2°C to 8°C for three consecutive batches as below: 170214LVF03 170222LVF04 170303LVF05
Document Details	• Valid Legalized GMP Certificate dated 29-11-2021 for M/s Middle East for Vaccines (MEVAC), General Organization for Veterinary Services, Ministry of Agriculture and Land Reclamation, Egypt valid till 28-11-2026. • Legalized FSC issued on 03-11-2021 issued by General Organization for Veterinary Services, Ministry of Agriculture and Land Reclamation, Egypt confirms that product is on free sales in the market of Egypt. • Copy of product specific sole agency agreement.

Remarks of Evaluator

Sr. No.	Observations	Response by the firm
1.	Evidence of locally registered product for applied product.	The firm has submitted following me-too: BIO-VAC LS-H120 (1000 and 2500 doses) manufactured by FATRO Italy, Local agent is Forward Solutions (Reg # 077560).
2.	Address of importer on DSL is different from Form-5A.	The firm has submitted revised Form-5A with correct address of applicant alongwith submission of fee 7500/- (slip No: 203221778) dated 03-11-2022.
3.	Finished product specification in the light of 267th Registration Board meeting minutes.	The firm has submitted finished product specifications as per Ph. Eur.
4.	Large Scale Clinical Data/Field Trial Data	The firm has submitted evaluation report of the safety and effectiveness after administration of the vaccine to target species i.e., commercial chickens under field conditions.
5.	Original or notarized copy of product specific sole agency agreement.	The firm has submitted notarized copy of sole agency agreement which declare that Bromed animal health as exculsive distributor for the territory of Pakistan.

	6. In virus name "Live attenuated Newcastle Disease Virus, strain LaSota [ME/NDV3]". What does word [ME/NDV3] mean? Is it name of strain or otherwise?	The firm has submitted that it is a Lasota Strain of New Castle disease virus, which is also mentioned on the free sales certificate, and (ME/NDV3) is a virus name inside MEVAC internal system.
	7. In virus name "Live attenuated Infectious Bronchitis Virus, strain classic H120 G-1[Eg/IBV2] What does word G-1[Eg/IBV2] mean? Is it name of strain or otherwise?	The firm has submitted that it is a Classical Strain of Avian Infectious Bronchitis virus, which is also mentioned on the free sales certificate, and (Eg/IBV2) is a virus name inside MEVAC internal system.
	Decision: Keeping in view the legalized free sale certificate (FSC) indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance of current Import Policy for finished drugs. • **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

77.	Name of Importer	**M/s BroMed Animal Health,** 246-A, West Wood Colony, Thokar Niaz Baig, District Lahore.
	DSL details	License to sell drugs as a distributor No.05-352-0066-037660D valid till 18-10-2022.
	Marketing authorization holder	M/s Middle East for Veterinary Vaccines (MEVAC), Second Industrial Zone-Extension part No. 21, 22, 24, 25 El Salhya El Gadeda, Elsharkya Governate, Egypt.
	Name of Manufacturer	M/s Middle East for Veterinary Vaccines (MEVAC), Second Industrial Zone-Extension part No. 21, 22, 24, 25 El Salhya El Gadeda, Elsharkya Governate, Egypt.
	Name of exporting country	Egypt
	Brand Name +Dosage Form + Strength	MEVAC Lasota + H120
	Diary No. Date of R& I & fee	Dy. No. 33062 (R&I) Dated 06-12-2021 Rs.150,000/- (Slip No. 6032929525)
	Composition	Each dose contains: Live attenuated Newcastle Disease Virus, LaSota strain ≥ $10^6EID_{50.}$ Live attenuated Classic Infectious Bronchitis Virus, H120 strain ≥ $10^{3.5}EID_{50.}$
	Pharmacological Group	Live viral veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	24 months (2°C -8°C)
	Pack size and demanded price	5000 dose vial / Decontrolled
	International availability	N/A
	Products already registered in Pakistan	BIO-VAC LS-H120 (1000 and 2500 doses) manufactured by FATRO Italy, Local agent is Forward Solutions (Reg # 077560)
	Stability data of finished product	The firm has submitted stability study data conducted at 2°C to 8°C for three consecutive batches as below: *170214LVF03* *170222LVF04*

	170303LVF05
Document Details	• Valid Legalized GMP Certificate dated 29-11-2021 General Organization for Veterinary Services, Ministry of Agriculture and Land Reclamation Egypt valid till 28-11- 2026. • Legalized FSC issued on 26-05-2021 issued by General Organization for Veterinary Services, Ministry of Agriculture and Land Reclamation Egypt confirms that product is on free sales in the market of Egypt. • Copy of product specific sole agency agreement.

Remarks of Evaluator

The firm has not submitted stability study data for applied pack size instead stability study data of 1000 dose vial is attached in this application.

Sr. No.	Observations	Response by the firm
1.	Evidence of locally registered product for applied product.	The firm has submitted following me-too: BIO-VAC LS-H120 (1000 and 2500 doses) manufactured by FATRO Italy, Local agent is Forward Solutions (Reg # 077560).
2.	Address of importer on DSL is different from Form-5A.	The firm has submitted revised Form-5A with correct address of applicant as per DSL alongwith submission of fee 7500/- (slip No: 65148336095) dated 03-11-2022.
3.	Finished product specification in the light of 267th Registration Board meeting minutes.	The firm has submitted finished product specifications as per Ph. Eur.
4.	Large Scale Clinical Data/Field Trial Data	The firm has submitted evaluation report of the safety and effectiveness after administration of the vaccine to target species i.e., commercial chickens under field conditions.
5.	Original or notarized copy of product specific sole agency agreement.	The firm has submitted notarized copy of sole agency agreement which declare that Bromed animal health as exclusive distributor for the territory of Pakistan.
6.	In virus name "Live attenuated Newcastle Disease Virus, strain LaSota [ME/NDV3]". What does word [ME/NDV3] mean? Is it name of strain or otherwise?	The firm has submitted that it is a Lasota Strain of New Castle disease virus, which is also mentioned on the free sales certificate, and (ME/NDV3) is a virus name inside MEVAC internal system.
7.	In virus name "Live attenuated Infectious Bronchitis Virus, strain classic H120 G-1[Eg/IBV2] What does word G-1[Eg/IBV2] mean? Is it name of strain or otherwise?	The firm has submitted that it is a Classical Strain of Avian Infectious Bronchitis virus, which is also mentioned on the free sales certificate, and (Eg/IBV2) is a virus name inside MEVAC internal system.

	Decision: Keeping in view the legalized free sale certificate (FSC) indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance of current Import Policy for finished drugs. Approval letter will be issued after compliance of following conditions: • **The firm shall submit stability study data of 5000 dose vial till claimed shelf life.** • **The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

78.	Name of Importer	**M/s Eros Pharmaceutical Pvt Ltd** Address: Plot No. 94-95, Sector 23, Korangi .Industrial Area, Karachi Pakistan
	DSL details	,License to sell drug as distributor No.533 Valid till 23-June-2023
	Marketing authorization holder	,M/s Jordan Bio Industries Center (Jovac) Amman, Yajouz road, near Yajouz Agriculture .Nursery, Amman, Jordan
	Name of Manufacturer	,M/s Jordan Bio Industries Center (Jovac) Amman, Yajouz road, near Yajouz Agriculture .Nursery, Amman, Jordan
	Brand Name + Dosage Form + Strength	LumpyShield-N Live vaccine with diluent
	Diary No. Date of R& I & fee	Dy. No. 29310 (R&I) Dated 17-10-2022 Rs.75,000/- (Slip No.8109531806)
	Composition	;Each dose (1 ml) vaccine contains Live Attenuated Lumpy Skin Disease Virus (Neethling Strain).....at least $10^{4.0}$ $TCID_{50}$
	Pharmacological Group	Veterinary Vaccine
	Type of Form	Form-5A
	Finished product specifications	Manufacturer's specifications
	Pack size and demanded price	Pack Size: 25 doses per vial Solvent : 25 ml (Normal saline) .Decontrolled
	Shelf life	Months 24 (Store at 2°C to 8°C
	International availability (Reference Regulatory Authority)	Jordan,Kenya,Bangladesh,Kuwait,Pakistan and .Yemen
	Products already registered in Pakistan	LumpySheild-N Vaccine 50 doses (Reg.No.111127
	Stability data of finished product	The firm has submitted stability study data of finished product for three batches at 2°C to 8°C. 13550 13240 13600 The firm has submitted stability study data of diluent for three batches at 2°C to 8°C. 422515 422615 422715
	General Documentation	**Free Sale Certificate (Original Legalized):** Manufacturer: M/s. Jordan Bio Industries Center (Jovac) Issued by: Ministry of Agriculture/ Veterinary and Animal Health Directorate, Department /Pharmacy

		and Drugs Control Division in Hashemite kingdom of Jordan Invalidation date: 17/06/2024. **Free Sale Certificate (Original Legalized) for diluent Normal saline:** Manufacturer: M/s. Jordan Bio Industries Center (Jovac) Issued by: Ministry of Agriculture/ Veterinary and Animal Health Directorate, Department /Pharmacy and Drugs Control Division in Hashemite kingdom of Jordan Invalidation date: 17/06/2024. **GMP Certificate (Original Legalized):** Issued to: M/s. Jordan Bio Industries Center Issued by: Ministry of Agriculture/ Veterinary and Animal Health Directorate, Department /Pharmacy and Drugs Control Division in Hashemite kingdom of Jordan. Validity: Three years from the date of inspection report i.e. 01-12-2020. **Sole Agency Agreement:** Sole agency agreement between Jordan Bio Industries Center and M/s Eros Pharmaceuticals (Private) Limited, is submitted by the firm.

:Remarks of Evaluator

The applied vaccine is an additional pack 25 doses of already approved vaccine .formulation (M-316)

Decision: Keeping in view the legalized free sale certificate (FSC) indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

79.	Name of Importer	**M/sHivet Animal Health Business**, Lahore 1st Floor, 667-P.M.A, Johar Town, Lahore, Pakistan
	DSL details	License to sell drug as distributor No.5-352-DD66-,040985D Valid till 21-Feb-2023
	Name of Manufacturer	M/s Beijing Sinder-Vet Technology Co., Ltd. Address: No.118, Shunyu Road, Beijing Tianzhu Airport Economic Development Zone, Shunyi District, Beijing, China.
	Brand Name + Dosage Form + Strength	SINVAC NDC killed
	Diary No. Date of R& I & fee	Dy. No. 18491 (R&I) Dated 01-07-2021 Rs.150,000/- (Slip No.010846616680)
	Composition	-:Each dose contains Newcastle disease antigen inactivated (La Sota (Strain (before inactivated virus content $\leq 10^{9.0}$ EID_{50}/0.1ml)
	Pharmacological Group	Veterinary vaccine
	Type of Form	Form-5A
	Finished product specifications	Ph. Eur. Specifications
	Pack size and demanded price	. Bottle; Decontrolled/500ml
	Shelf life	Months 18 ((Store at 2°C to 8°C
	Products already registered in	Avipro 105 ND Chick of Golden Harvest (Reg #

Pakistan	077533).
Stability data of finished product	The firm has submitted stability study data of finished product for three batches for 18 months at 2°C to 8°C. 201502005 201503001 201503002
General Documentation	**Free Sale Certificate (Original Legalized):** Manufacturer: M/s. Beijing Sinder-Vet Technology Co., Ltd Issued by: Animal Husbandry and Veterinary Bureau of Zhucheng City Issue date: 12-01-2022. **GMP Certificate (Original Legalized):** Certificate No: 01010 Issued to: M/s. Beijing Sinder-Vet Technology Co., Ltd Issued by: Beijing Bureau of Agriculture and Rural Affair Issued date: 29-11-2021 **Sole Agency Agreement:** Sole agency agreement between Beijing Sinder-Vet Technology Co., Ltd and M/s Hivet Animal Health Business, is submitted by the firm.

:Remarks of Evaluator

Initially, the firm had applied for Chinese Veterinary pharmacopoeia specifications. Upon query, the firm has revised to Ph. Eur. Specifications without submission of applicable .fee

Decision: Keeping in view the legalized free sale certificate (FSC) indicating product availability in the country of origin and legalized GMP certificate, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

(Deferred cases)
Imported Veterinary Biologicals from Non-Reference Countries

80.	**Name of Importer**	**M/s ICI Pakistan Ltd,** Pharmaceutical Business, ICI House No.5 West Wharf, Karachi 7400
	DSL details	License to sell drug as distributor No.020 valid till 10-03-2023 .
	Name of Manufacturer	M.s.Choong Ang Vaccine Laboratories Co., Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon, 34055, Korea.
	Brand Name + Dosage Form + Strength	**PoulShot® IB-Castle** Lyophilized Solution 2000 Doses / vial
	Type of Form	Form 5-A
	Dy. No. Date of Application, Fee submitted	Dy. No.14754(R&I) Dated 24-06-2020, Dy. No.11891(R&I) Dated 21-04-2021. Rs.100,000/- dated 17-06-2020
	Composition	Each dose contains: Newcastle Disease virus (NDV, NDRL0901 strain) ≥ $10^{6.0}EID_{50}$

		Infectious bronchitis virus (IBV, AVR1/08 strain) : ≥ $10^{6.0}EID_{50}$
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Live viral veterinary vaccine
	Shelf life	24 Months (Store at 2°C -8°C)
	Demanded Price / Pack size	2000 Doses / Vial, Decontrolled
	Products already registered in Pakistan	The combination is available but strains mentioned are not available as per record.
	General Documentation	• Legalized FSC having Certificate No.M196216 issued by Animal & Plant Quarantine Agency of the Ministry for Agriculture Food & Rural Affairs of Korea dated 12-11-2019. • Legalized GMP Certificate issued by Animal & Plant Quarantine Agency of Korea dated 27-02-2020.
	Previous Decisions:	Registration Board referred the case to Expert Working Group on Veterinary Drugs **(M-307)**. Referred the product to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan **(M-313)**. Deferred for confirmation of availability of such combination in reference regulatory authorities **(M-317).**
	Evaluation by DBE&R	**Recommendations by Assistant Animal Husbandry Commissioner:** Routine combination already many companies have this combination, therefore, may be recommended for import. The firm has submitted that our product is a veterinary vaccine, registered and freely available in Korea and as per recommendations by Assistant Animal Husbandry Commissioner similar vaccine is already available in Pakistan. We have reviewed the Registration Board minutes and could not find a requirement of availability in reference regulatory authority for veterinary medicine / vaccine (Extract of decisions on various products attached).

Decision: Registration Board deferred the case for following:

- **Status of applied strains in reference regulatory authorities as adopted by Registration Board in its 275th meeting.**
- **Characteristics of strain worth considering in Pakistan.**

81.	**Name of Importer**	**M/s ICI Pakistan Ltd,** Pharmaceutical Business, ICI House No.5 West Wharf, Karachi 7400
	DSL details	License to sell drug as distributor No.020 valid till 10-03-2023 .
	Name of Manufacturer	M.s.Choong Ang Vaccine Laboratories Co., Ltd. 1476-37 Yuseong-daero, Yuseong-gu, Daejeon, 34055, Korea.
	Exporting country	Korea
	Brand Name + Dosage Form + Strength	**PoulShot® Qx Flu-5** Injectable Solution 1000 doses / bottle
	Type of Form	Form 5-A

Dy. No. Date of Application, Fee submitted	Dy. No.14758(R&I) Dated 24-06-2020, Dy. No.11891(R&I) Dated 21-04-2021 Rs.100,000/- dated 17-06-2020
Composition	Each dose contains: Newcastle disease virus (NDV, LaSota strain) ≥ $10^{8.0}EID_{50}$ Infectious bronchitis virus (IBV, KM91 strain) ≥ $10^{6.0}EID_{50}$ Infectious bronchitis virus (IBV, ADL05258 strain) ≥ $10^{6.0}EID_{50}$ Egg drop syndrome virus (EDSV, K11 strain) ≥ $10^{5.5}EID_{50}$ Avian influenza virus (AIV H9N2, 01310 strain) ≥ $10^{8.0}$ EID_{50}
Finished product specifications	As per innovator's Specifications
Pharmacological Group	Inactivated viral veterinary vaccine
Shelf life	24 Months (Store at 2°C -8°C)
Demanded Price / Pack size	1000 Doses / Vial, Decontrolled
Products already registered in Pakistan	The combination is available but strains mentioned are not available as per record.
General Documentation	• Legalized FSC having Certificate No. M2003187 issued by Animal & Plant Quarantine Agency of the Ministry for Agriculture Food & Rural Affairs of Korea dated 12-03-2020. • Legalized GMP Certificate issued by Animal & Plant Quarantine Agency of Korea dated 27-02-2020.
Previous Decisions:	Registration Board referred the case to Expert Working Group on Veterinary Drugs **(M-307)**. Referred the product to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the strain in Pakistan **(M-313)**. Deferred for confirmation of availability of such combination in reference regulatory authorities **(M-317).**
Evaluation DBE&R	**Recommendations by Assistant Animal Husbandry Commissioner:** Already one such combination is available in Pakistan. It's good combination may be recommended for import to make healthy combination. The firm has submitted that our product is a veterinary vaccine, registered and freely available in Korea and as per recommendations by Assistant Animal Husbandry Commissioner similar vaccine is already available in Pakistan. We have reviewed the Registration Board minutes and could not find a

requirement of availability in reference regulatory authority for veterinary medicine / vaccine (Extract of decisions on various products attached).

Decision: Registration Board deferred the case for following:

- **Status of applied strains in reference regulatory authorities as adopted by Registration Board in its 275th meeting.**
- **Characteristics of strain worth considering in Pakistan.**

Miscellaneous Cases:

The following product was approved in 257th meeting of Registration Board and during the processing of the case, the firm informed that the manufacturing site of their product abroad has been changed from Address: **"**No.8, Jingsheng North 3rd Street, Golden Bridge Science, Industrial Base, Tongzhou District Beijing,China.**"** to Address : **"**No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing, China**"**. Now the firm has submitted fresh dossier of with full Fee which is placed before the board for consideration.

82.	Name, address of Applicant / Importer	**M/s Getz Pharma (Pvt.) Ltd**. Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan.
	Details of Drug Sale License of importer	M/s Getz Pharma (Pvt.) Limited. Plot No.: 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan. License No.: 570 Valid till: 16-08-2024
	Name and addressof marketing authorization holder (abroad)	Name: Gan & Lee Pharmaceuticals, Address: No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing, China.
	Name, address of manufacturer(s)	Name: Gan & Lee Pharmaceuticals, Address: No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP certificate (No. 20200290) valid till 02.08.2022 issued by Beijing Municipal Medical Products Administration for Recombinant Insulin Glargine Injection, Solution for injection. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market in exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection in every 1 year.
		DML: Firm has submitted copy of Drug Manufacturing License of manufacturer (No. J.20150012) issued by Medical Product Administration of Beijing. The certificate is valid till 17-11-2025.
	Details of letter of authorization / sole agency agreement	Firm has submitted a copy of letter of authorization from Director of Gan & Lee

		Pharmaceuticals. According to the letter, the firm Gan & Lee Pharmaceuticals authorizes "Getz Pharma (Pvt.) Limited with its place of business at Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi, Pakistan as their business representative with undisputed powers authorized to deal with the product registration of Basagine, Insulin Glargine Injection (3 mL: 300 IU / Cartridge) in Pakistan as per mutually agreed terms and conditions by both companies. The letter was issued on August 26th, 2020. Further, firm has submitted sole agency Agreement between Getz Pharma (Pvt.) Limited and Gan & Lee Pharmaceuticals issued on October 23, 2020 valid for 05 years from date of issue.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and Date of submission	Dy. No. 19551 Dated 04-07-2022
	Details of fee submitted	PKR 150,000/- dated 12.05.2022
	The proposed proprietary name / brand name	**BASAGINE Solution for Injection 100 IU/mL in 3ml Cartridge.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Recombinant Insulin Glargine……....100 IU (3mL cartridge)
	Pharmaceutical form of applied drug	Colorless sterile solution in 3ml Cartridge.
	Pharmacotherapeutic Group of (API)	Insulins and Analogues for injection, long-acting (ATC Code: A10AE04)
	Reference to Finished product specifications	USP specifications
	Proposed Pack size	1's in 3ml cartridge 3's in 3ml cartridge 5's in 3ml cartridge

	Proposed unit price	As per DPC
	Shelf Life	36 Months
	Storage Condition	Store between 2°C to 8°C
	The status in reference regulatory authorities	Lantus Solostar Injection 100units/mL (Sanofi Aventis US)
	For generic drugs (me-too status)	Lantus Optiset Injection 100units/mL (Sanofi-Aventis Pakistan Limited, Karachi) Reg. No.: 031389
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Name: Gan & Lee Pharmaceuticals Address: No. 8 Nanfeng West 1st Street, Huoxian, Tongzhou District, Beijing, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of both API at accelerated and real time conditions. The real time stability data is conducted at -15°C ~ -20°C for 48 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted Assay Method Validation by performing linearity, accuracy, precision, and robustness.

	Container closure system of the drug product	Insulin glargine injection consist of a prefilled 3mL Type I glass cartridge. The cartridge is closed at one end with a bromobutyl rubber plunger and sealed at the other end with a combiseal consisting of a rubber liner in an aluminum cap. Further packed in secondary carton along with package insert.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5±3°C for 36 months. 121807011 121807021 121807031
	Module IV	Detailed in Biosimilarity data mentioned below
	Module V	Detailed in Biosimilarity data mentioned below
	The firm has submitted Biosimilarity data as per following details:	
WHO Biosimilarity Guidelines	**Data Submitted by M/s Gtz Karachi**	

<table>
<tr><td>Quality Comparison Physicochemical Characterization</td><td>Insulin Glargine from Gan & Lee has been compared with Lantus – Reference Listed Drug (RLD)
<table>
<tr><th>Category</th><th>Quality Attributes</th><th>Analytical methods</th></tr>
<tr><td rowspan="2">Primary structure</td><td rowspan="2">Amino acid sequence</td><td>Intact molecular weight</td></tr>
<tr><td>Peptide mapping and full-length sequencing by LC-MS/MS</td></tr>
<tr><td rowspan="2">Higher order structure</td><td>Disulfide bond mapping</td><td>Partial reduction and LC-MS</td></tr>
<tr><td>Free thiols</td><td>Ellman's assay</td></tr>
<tr><td></td><td>Secondary, tertiary and quaternary structures</td><td>Far/Near-CD, fluorescence spectroscopy</td></tr>
<tr><td rowspan="3">Charge heterogeneity</td><td rowspan="3">Charge variant</td><td>Cation exchange chromatography</td></tr>
<tr><td>Capillary zone electrophoresis</td></tr>
<tr><td>Imaged capillary isoelectric focusing (iCIEF)</td></tr>
<tr><td>Hydrophobicity heterogeneity</td><td>Hydrophobic variants</td><td>Hydrophobic interaction chromatography</td></tr>
<tr><td>Size heterogeneity</td><td>LMW and HMW impurities</td><td>Size exclusion chromatography coupled with multi-angle light scattering (SEC-MALS)</td></tr>
<tr><td>In-solution stability</td><td>T_m</td><td>Differential scanning calorimetry (DSC)</td></tr>
<tr><td>In-solution particle size homogeneity</td><td>Average size</td><td>Dynamic light scattering (DLS)</td></tr>
<tr><td rowspan="2">In-Vitro Biofunctionality</td><td>Receptor binding assay</td><td>Surface Plasmon Resonance (SPR)</td></tr>
<tr><td>Cell-based bioactivity assay</td><td>INSR/IGF-1R receptor phosphorylation assay</td></tr>
</table></td></tr>
<tr><td>Biological Activity</td><td>Cell based Bioactivity Assay – Receptor Phosphorylation Assay
The assay based on the HTRF technology provided by Cisbio mainly, aimed to develop a method that can detect the level of Insulin Receptor. Besides the phosphorylation level of IGFIR (Insulin like Growth Factor I Receptor) was detected based on Alpha technology provided by PerkinElmer.</td></tr>
<tr><td>Immunochemical properties</td><td>To evaluate the immunogenicity of Insulin Glargine Injection (Gan & Lee, China) in patients with diabetes mellitus, compared to Lantus Injection (Sanofi-Aventis, Germany). The immunogenicity will be evaluated based on the respective endpoints as:</td></tr>
</table>

	- Incidence of immune response (formation of antibodies against insulin) in the groups of the study drug and comparison drug in %; - Comparison of the mean antibody titer in the studied groups; - Analysis of the dynamic changes of the antibody titer after the end of treatment and during the treatment compared to the screening data.
Impurities	Product/Process-related Impurities - Cell Substrate-derived Impurities - Single-chain Precursor - Related Proteins - High Molecular Weight Proteins - Inorganic Impurities
Stability Studies	The firm has submitted stability studies.
Non-clinical Comparison **In-vitro Studies** **In-vivo Studies** **Biological / Pharmacodynamic activity** **Non- clinical Studies**	**Non-comparative:** Safety Pharmacology: Effects on Central Nervous System, Cardiovascular System, Respiratory System Primary Pharmacodynamics: Effect of insulin glargine injection to lower blood glucose in normal rabbits. Safety Pharmacology: Hypersensitivity and Skin Irritation Test The study was to observe the hypersensitivity of insulin glargine injection in guinea pigs and skin irritation test at the injected site in rabbits. **Comparative evaluation** of toxicity and toxicokinetic Characteristic of Insulin Glargine Injection following 28 day repeated subcutaneous doses in Spargue Dawley Rats.
Clinical Studies	To compare the pharmacokinetic and pharmacodynamic properties of Insulin Glargine injection (Gan & Lee - China) with Lantus in healthy subjects. Open label, comparative, randomized, multicenter clinical study of the efficacy, safety and immunogenicity of Insulin Glargine solution for subcutaneous injection 100U/ml (Gan & Lee - China) and Lantus solution for subcutaneous injection 100U/ml (Sanofi Aventis - Germany), in patients with diabetes mellitus. (Phase III clinical trial, Patients 118.)
Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin and GMP status of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

Deferred cases:
Locally manufactured Enoxaparin Injections (Form-5)

83.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20th-05-2021 valid up to 19th-05-2023

	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. NO.1236, NAN'ER ROAD, DONGYING CITY, SHANDONG PROVINCE, CHINA
	Brand Name + Dosage Form + Strength	**Clotenox Injection 20mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……20mg
	Finished product specifications	BP Spec
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Lovenox the product is available in PFS in the said strength & volume.
	Products already registered in Pakistan	Clexane 20mg/0.2ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of Application, Fee submitted	Dy.No. dated 13-12-2018. Fee Submitted: Rs.20,000/- dated 06-11-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.2ml PFS is available in reference country.
84.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20th-05-2021 valid up to 19th-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox Injection 40mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……40mg
	Finished product specifications	BP Spec
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Lovenox the product is available in PFS in the said strength & volume.
	Products already registered in Pakistan	Clexane 40mg/0.4ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of	Dy.No. dated 13-12-2018.

	Application, Fee submitted	Fee Submitted: Rs.20,000/- dated 06-11-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.4ml PFS is available in reference country.
85.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20th-05-2021 valid up to 19th-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox Injection 60mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……60mg
	Finished product specifications	BP Spec
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Lovenox the product is available in PFS in the said strength & volume.
	Products already registered in Pakistan	Clexane 60mg/0.6ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of Application, Fee submitted	Dy.No. dated 13-12-2018. Fee Submitted: Rs.20,000/- dated 06-11-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.6ml PFS is available in reference country.
86.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20th-05-2021 valid up to 19th-05-

		2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox Injection 80mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……80mg
	Finished product specifications	BP Spec
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Lovenox the product is available in PFS in the said strength & volume.
	Products already registered in Pakistan	Clexane 80mg/0.8ml but the product is available in PFS
	Type of Form	Form 5
	Dy. No. Date of Application, Fee submitted	Dy.No. dated 13-12-2018. Fee Submitted: Rs.20,000/- dated 06-11-2018.
	Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
	General Documentation	The formulation in 0.8ml PFS is available in reference country.
87.	**Name of Manufacturer**	**M/s Nextar Pharma (Pvt) Ltd** **Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.**
	DML and last GMP details	DML No. 000777 Address: Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi. **Evidence of section:** Injectable Ampoule and Pre-filled Syringe (biological) section dated 3rd June, 2021 GMP: Last GMP conducted on 20th-05-2021 valid up to 19th-05-2023
	Bulk Manufacturer	DONGYING TIANDONG PHARMACEUTICAL CO., LTD. No.1236, Nan-er Road, Dongying City, Shandong Province, China (Small-Volume Injection **(Injection workshop, pre-fill production line**)
	Brand Name + Dosage Form + Strength	**Clotenox Injection 100mg PFS**
	Composition	Each Pre-Filled Syringe contains: Enoxaparin Sodium……100mg
	Finished product specifications	BP Spec
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Lovenox the product is available in PFS in the said strength & volume.
	Products already	Clexane 100mg/1ml but the product is available in PFS

registered in Pakistan	
Type of Form	Form 5
Dy. No. Date of	Dy.No. dated 13-12-2018.
Application, Fee submitted	Fee Submitted: Rs.20,000/- dated 06-11-2018.
Demanded Price / Pack size	ml Pre-Filled Syringe / As per DPC 1
General Documentation	The formulation in 1 ml PFS is available in reference country.

Data as per guidelines of 289th meeting of Registration Board;

ii) For Bulk Concentrate Import, Local formulation Filling:

i.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Legalized GMP Certificate No.SD 20180757 dated 30-08-2018 issued by Shandong Food and Drug Administration, China valid till 29-08-2023. Manufacturer and its address: Dongying Tiandong Pharmaceutical Co., Ltd. No.1236, Nan-er Road, Dongying City, Shandong Province, China.
ii.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Legalized FSC (Certificate No.: 2018-001) dated 01-08-2018 issued by Shandong Food and Drug Administration of People's Republic of China.
iii.	The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the similar efficacy and safety to innovator product covering following requirements:	
	f) The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	The firm has submitted physicochemical Characterization performed by the bulk manufacturer. The comparison has not been performed with innovator. 1.Molecular mass and molecular mass distribution. 2.HPLC-MS 3.NMR • 1H NMR: • 13C NMR: 4.UV: 5.Sodium content 6. Molar ratio of sulfate ions to carboxylate ions

g)	The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	**Equivalence of heparin source material:** R: The starting material of generic Enoxaparin (manufactured by Tiandong) is porcine crude heparin, and no ruminant gene is detected as per qPCR.
h)	The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.	**Not submitted**
i)	The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	**Not submitted**
j)	The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and Anti-IIa profiles.	**Not submitted**
iv.	The firm shall provide the lot release certificate of the finished product manufactured by same	Not Applicable

	bulk concentrate/ ready to fill from country of export (If applicable).	
v.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	The stability studies performed by API manufacturer for drug substance for 24months real time stability study data at 25°C±2°C, 60%RH±5% RH & 6 months accelerated stability study at 40°C±2°C, 75%RH ±5% RH and the results found satisfactory against the specified specification limits.
vi.	The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.	Testing of Enoxaparin sodium was performed as per pharmacopeial method and results complies with specifications and the data has been submitted. i.e. • Identification by: - Size-Exclusion Chromatography (RP-HPLC) - Ratio of anti-factor Xa activity to anti-factor IIa activity - Sodium salt Assay: - Anti-factor Xa Activity - Anti-factor IIa Activity • Clarity and colour of solution • Acidity or alkalinity • Light absorption • Related Substances by HPLC • Sodium • Bacterial Endotoxins
vii.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months stability data on all the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.	The firm has submitted three trial batches for each strength i.e. 20mg, 40mg, 60mg, 80mg, 100mg conducted at 30°C ± 2°C/65% ± 5%RH for the finished biological product. The stability studies have performed till shelf life stability (24 months) as per pharmacopoeial monograph of enoxaparin sodium injection and results found within the specified limits.
viii.	The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used: a. SDS-PAGE for individual proteins b. GC-MS for lipid impurities c. Threshold ® Total DNA Assay System for DNA content.	Related substances by HPLC: Purity of LMWHs have been demonstrated by using Anion Exchange chromatography based test in comparison with innovator product i.e. Clexane Injections.
ix.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if	Not Submitted

	there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	
x.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	The firm has submitted undertakings as detailed in 289th meeting of Registration Board by the local manufacturer.
xi.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm has submitted undertaking if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.
xii.	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm has submitted undertaking If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.
xiii.	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertakings All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.

Remarks of Evaluator:

Sr. No.	**Decision of 321st meeting of RB**	**Response by the firm**
1.	The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethyl ammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	**Physicochemical Characterization performed with innovator product by the bulk manufacturer:** 1. **Molecular mass and molecular mass distribution**. Size exclusion chromatography is used to detect molecular mass, characterizing the distribution and proportion of enoxaparin sodium oligosaccharide chain length and data is comparable between Lovenox (Branded) and generic Enoxaparin Sodium (Manufactured by Tiandong). 2. **HPLC-MS** MS spectra of generic Enoxaparin and branded Lovenox are submitted. The retention time and mass to charge ratio

		are comparable to oligosaccharide peak and oligosaccharide sequence. 3. **NMR** • ^{1}H NMR: Spectra obtained are similar to that obtained with Enoxaparin Sodium reference standard • ^{13}C NMR: Spectra obtained are similar to that obtained with Enoxaparin Sodium reference standard 4.**UV:** The maximum UV absorption wavelength of both generic Enoxaparin and brand Lovenox is 232 nm, and specific absorption coefficient falls within specified range. 5. **Sodium content** The sodium content of generic Enoxaparin (Manufactured by Tiandong) and branded Lovenox are within 11.3% to 13.5%. 6. **Molar ratio of sulfate ions to carboxylate ions** The molar ratio of sulfate ions to carboxylate ions of generic Enoxaparin and branded Lovenox are no less than 1.8.
2.	The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	Enoxaparin sodium is the sodium salt of a low-molecular-mass heparin that is obtained by alkaline depolymerization of the benzyl ester derivative of heparin from porcine intestinal mucosa. Enoxaparin consists of a complex set of oligosaccharides that have not yet been completely characterised. Based on current knowledge, the majority of the components have a 4-enopyranose uronate structure at the non-reducing end of their chain. 15 per cent to 25 per cent of the components have a 1,6-anhydro structure at the reducing end of the chain. The mass-average relative molecular mass ranges between 3,800 and 5,000, with a characteristic value of about 4,500. The degree of sulfation is about 2 per disaccharide unit. The potency is not less than 90 IU and not more than 125 IU of anti-Factor Xa per milligram, calculated with reference to the dried substance. The anti-factor IIa activity is not less than 20.0 IU and not more than 35.0 IU per milligram,

calculated with reference to the dried substance.

First, crude heparin (i.e., the starting material) through enzymolysis, centrifugation and then, following a series of purification processes, is purified to obtain heparin sodium (i.e., Intermediate I). After that, through salification, the Intermediate I is converted to benzethonium heparinate (i.e., Intermediate II). After that, through esterification, the Intermediate II is converted to heparin benzyl ester (i.e., Intermediate III), then, Enoxaparin sodium is formed by alkaline degradation. Following a series of purification process (filtering, precipitating, decoloring, filtering, lyophilizing, milling and blending, packaging, and examining), the final product (Enoxaparin sodium API) is obtained.
The starting material of generic Enoxaparin
(manufactured by Tiandong) is porcine crude heparin, and no ruminant gene is detected as per qPCR.

3. The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.

- Size exclusion chromatography is used to detect the molecular mass, characterizing the distribution and proportion of Enoxaparin sodium oligosaccharide chain length.
- Oligosaccharide sequence determined by HPLC-MS.
- Sulfated disaccharide structure by ^{1}H NMR, ^{13}C NMR.
- Specific absorption coefficients by UV.
- Molar ratio of sulfate ions to carboxylate ions by titration.
- Sodium content by Atomic Absorption.

Via above provided tests, equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species have been submitted.

4. The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin

APTT test:
The APTT value is related to the Enoxaparin sodium concentration, the higher the concentration, the longer the

	time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	APTT value. There is no significantly difference of the APTT value between generic Enoxaparin (manufactured by Tiandong) and brand LOVENOX. **Anti-Xa activity and Anti-IIa activity test**: The Anti-Xa activities and Anti-IIa activity of generic Enoxaparin (manufactured by Tiandong) and brand LOVENOX are within the specification range of 90 IU/mg~125 IU/ mg (dry basis) and 20 IU/mg~35 IU/mg (dry basis) respectively; Anti-Xa/ Anti-IIa value of Generic Enoxaparin (manufactured by Tiandong) and brand LOVENOX are also within the specification range of 3.3~5.3.
5.	The fifth criterion for establishing sameness of enoxaparin is equivalence of *ex-vivo* pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of *in vivo* anti-Xa and Anti-IIa profiles	The firm has Submitted bioequivalence study reports Open, Randomized, Single Dose, two period crossover bioequivalence trial under fasting conditions on healthy subjects. 24 subjects enrolled in the group according to the screening number of the subjects in ascending order. The statistician provides a random allocation table and randomly allocates the subjects to one of the two dosing sequence A (T-R) group or the B (R-T) group in a 1:1 ratio, with the same number of subjects in each dosing sequence. Test preparation: Enoxaparin sodium Injection 0.6 mL: 6000 AxaIU; Reference preparation: Enoxaparin sodium Injection 0.6 mL: 6000 AxaIU. The test preparation Enoxaparin sodium injection (0.6 mL: 6000 AxaIU) developed and produced by Dongying Tiandong Pharmaceutical Co., Ltd. and the brand reference preparation Clexane® (Enoxaparin sodium injection, 0.6 mL: 6000 AxaIU) were found bioequivalent in Chinese healthy subjects under fasting subcutaneous injection.
6.	The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used:	The firm has submitted that comparative impurity testing for enoxaparin has been performed as per British Pharmacopoeia. Tests of related substances by HPLC has been submitted in comparison with innovator product i.e. Clexane Injections.

a. SDS-PAGE for individual proteins
b. GC-MS for lipid impurities
c. Threshold ® Total DNA Assay System for DNA content.

7.	Agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	The firm has submitted process change declaration from source (Dongying Tiandong Pharmaceutical Co. Ltd) stating that we would inform for the critical process changes related to the product and implement only after approval.
8.	Commitment that "If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Submitted.
9.	Commitment that "All the provisions as contained in the Drugs Act, 1976 and rules made thereunder including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to".	Submitted.

Remarks of Evaluator:
The firm has provided Pre-filled syringe Biological Section. Already registered products are as under:

1. Nexfil 300 (Filgrastim)
2. Pegaron Inj. (Pagylated Interferon alpha 2a)
3. NP-POETIN (Erythropoietin)

Decision: Registration Board deferred the case for submission of section wise details of products of M/s Nextar Pharma (Pvt) Ltd., Karachi in the biological facility.

Cases of AD-II (Mr. Saadat Ali Khan)

A: Imported Human Biological product from Reference countries/WHO PQ:

88.	**Name, address of Applicant / Importer**	**HealthBee Projects Private Limited** **Address: Office 202, 2nd floor, Business Heights II, Plot no 133, Civic Center, Phase IV, Bahria Town, Islamabad**
	Details of Drug Sale License of importer	**License No:** 01-374-0176-065437D **Address:** Ground Floor, Momi Plaza, Plot no 43, Business Square Phase 7, Bahria Town, District Rawalpindi **Address of go-down:** Ground Floor, Momi Plaza, Plot no 43, Business Square Phase 7, Bahria Town, District Rawalpindi **Validity: 10.03.2023**
	Name and address of marketing authorization holder (abroad)	Beijing Institute of Biological Products Co., Ltd Manufacturing Address: No 6&9 Boxing 2nd Road, Economic Technological Development, Area, Beijing, P.R China Registration Address: Room 205, Second Floor, Building 4. No. 9

		Boxing 2nd Road, Economic-Technological Development Area, Beijing P.R China
	Name, address of manufacturer(s)	Beijing Institute of Biological Products Co., Ltd Manufacturing Address: No 6&9 Boxing 2nd Road, Economic Technological Development, Area, Beijing, P.R China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (No Beijing 20220116) issued on 17th August 2022 **by Beijing Municipal Medical Product Administration** The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: 1 years)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization dated 30th June 2022 from Beijing Institute of Biological Products Co., Ltd The letter specifies that the manufacturer appoints HealthBee Projects Private Limited to register & sell their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.28917 Dated: 12.10.2022
	Details of fee submitted	Rs. 150030/- Dated 21/9/2022
	The proposed proprietary name / brand name	Poliomyelitis Vaccine (Vero Cell), Inactivated, Sabin Strains 1 dose (0.5ml)/vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains Inactivated poliovirus **Type I (Sabin): 15DU** **Type II (Sabin): 45DU** **Type III (Sabin): 45DU**

	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Inactivated vaccine (IPV)
	Reference to Finished product specifications	In house
	Proposed Pack size	0.5ml/vial, 1 vial/box, 3 vials/box and 10 vials/box
	Proposed unit price	Retail price as per SRO
	Shelf Life	24 months
	Storage Conditions	$2^{O}C$ -$8^{O}C$
	The status in reference regulatory authorities	WHO PQ
	For generic drugs (me-too status)	Sanofi Pasteur (Imovex) Bilthoven Biologicals IPV
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance & drug product.
	Name, address of drug substance manufacturer	Beijing Institute of Biological Products Co., Ltd Manufacturing Address: No 6&9 Boxing 2^{nd} Road, Economic Technological Development, Area, Beijing, P.R China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturer description of manufacturing process and control, impurities, specifications, analytical procedure and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Drug substance at accelerated as well as real time conditions. Real time stability data: 2-$8^{O}C$ for 24 months, Accelerated stability data: 20-$25^{O}C$ for 4 weeks
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process control, process validation protocol, control of excipients, control of drug product, specification, analytical procedures, verification, batch analysis, justification of specification, reference standard or materials container closure system and stability

	Analytical method validation/verification of product	Firm has submitted analytical method validation/ verification of product including accuracy, stability, precision, and solution stability
	Container closure system of the drug product	The final container closure system is film coated middle borosilicate glass vial, film coated brominated butyl rubber stopper,
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions. The real time stability data is conducted at $2^{O}C$ -$8^{O}C$ for 24 months. The accelerated stability data provided is of 03 batch and is conducted at at 25°C for 06 months.
	Module-IV	• Rats Immunogenicity Study for sIPV (Pre-clinical). • Single Dose Toxicity Study on ICR Mice with Intramuscular Injection and Intravenous Injection of sIPV • Repeat-dose Toxicity Study on Macaca Fascicularis with Intramuscular Injection of sIPV, 12 Weeks and 8-Week Recovery. • Systemic Active Anaphylaxis Study on Guinea Pigs Immunized with sIPV.
	Module-V	• The Phase I trial was to evaluate its safety, it was evaluated on adults aged 18-45 years old, 4 years old aged group and infants aged 2 months old group in the order of low, middle and high dosage. • The Phase II trial is a single-blind, randomized, controlled study in which approximately 500 healthy new born infants will be enrolled and allocated across five arms. • The Phase III trial is a single-blind, randomized, controlled study in which approximately 1200 healthy new born infants will be enrolled and allocated across two arms. • Phase IV clinical study was initiated by BIBP in Henan CDC to assess the safety, immunogenicity and lot-to-lot consistency of 3 lots of sIPV and non-inferiority in comparison to a WHO prequalified comparator wlPV (Sanofi Pasteur). • A Phase IV clinical study was initiated to evaluate the safety and immunogenicity of coadministration of sIPV and DTaP. • A Phase IV clinical study was initiated by BIBP to immunogenicity of sIPV-bOPV-bOPV, sIPV-sIPV-bOPV, sequential immunization schedule.
	Remarks	
	Decision: Keeping in view legalized CoPP and WHO Prequalification (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	
89.	**Name, address of Applicant / Importer**	Vikor Enterprises Plot # Z2-A, S.I,T.E. Manghopir Road , Karachi

	Details of Drug Sale License of importer	License No: 193 Address: Plot No. Z2-A, S.I.T.E. Manghopir Road Karachi Address of go-down: Plot F-24, S.I.T.E. Karachi Validity: 08-04-2023 Status: Valid
	Name and address of marketing authorization holder (abroad)	Bharat Biotech International Limited Genome Valley, Shameerpet, Mandal, Medchal District- 500078, Telangana India.
	Name, address of manufacturer(s)	M/S Bharat Biotech International Limited, Genome Valley, Shameerpet, Mandal, Medchal District- 500078, Telangana India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original legalized COPP (No. 2117/STORES/2019-40) issued on 09-07-2019 by Drug Control Administration Government of Telangana India **valid upto 03-04-2022.** The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: Not less than once in a year)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization original legalized dated 18-06-2019 from Bharat Biotech International Limited. The letter specifies that the manufacturer exclusively authorized M/s Vikor Enterprises (Pvt) Ltd.Karachi to distribute, market , promote their mentioned products along with registration of the product in Pakistan..
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3916 dated 10-02-2022
	Details of fee submitted	Fee of Rs. 75,000/ dated 09-02-2022 Slip No. 406921749277
	The proposed proprietary name / brand name	**Rotavac** Rotavirus vaccine (live, oral) BP 5mL (Multidose) vial

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5ml (5 drops) contains: Vero cell derived Rotavirus 116E live Attenuated Bulk….. Not less than (NLT) $10^{5.0}$ FFU
	Dosage form of applied drug	Liquid in frozen form
	Pharmacotherapeutic Group of (API)	Live viral Vaccine
	Reference to Finished product specifications	BP Sepecification
	Proposed Pack size	5.0 ml Multi dose Vial
	Proposed unit price	Retail price: As per DPC
	Shelf Life	60 months
	Storage Conditions	-20 ^{O}C +5 ^{O}C
	The status in reference regulatory authorities	The product is WHO PQ as record available at WHO website accessed on 24th November, 2022. https://extranet.who.int/pqweb/content/rotavac-0
	For generic drugs (me-too status)	Rota virus in 10 dose is not registered as per available record.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance & drug product.
	Name, address of drug substance manufacturer	M/S Bharat Biotech International Limited, Genome Valley, Shameerpet, Mandal, Medchal District 500078, Talangana India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The real time stability data of Rotavirus 116E Live has conducted at -70 C +/-5C for 120 months and at -20 C +/-5C for 48 months. The accelerated stability studies conducted at +5 C +/- 3C for 12 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted Analytical test method along with validation studies of the drug product.
	Container closure system of the drug product	Filled in 5 ml tubular glass vial having 20 mm neck of USP type I with 20 mm grey bromobutyl rubber stopper (RFU) sealed with 20 mm tear lift flip down (RFU) transparent violet colour seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions. The real time stability data is conducted at -20 ^{O}C +5 ^{O}C for 60 months. The accelerated stability data provided is of 03 batch and is conducted at at 5°C ± 3°C for 06 months.
	Module-IV	The firm has submitted repeat dose toxicity study on Harlan Sprague Dawley Rats and New Zealand white rabbits.
	Module-V	i. Double blind Randomized Placebo controlled dose escalating Phase Ib/IIa Study to evaluate the safety and Immunogenicity of Live Attenated Rotavirus vaccine in Healthy Non Malnourished Infant 8-20 Weeks of Age. ii. A Phase III Randomized double blind placebo controlled trial to evaluate the protective efficacy of three doses of oral rotavirus vaccine (ORV) 116E, against severe rotavirus gastroenteritis in infants (**6799 Subjects**) iii. A Phase III Randomized double blind placebo controlled trial to evaluate the Non-interference in the Immune Response og three doses of oral rotavirus vaccine (ORV) 116E to Antigens contained in childhood vaccinre and to assess the clinical Lot Consistency of three production Lots.
	Remarks	a. CoPP is expired on **valid upto 03-04-2022** while was valid at the time of submission of the application.
	Decision: Keeping in view legalized CoPP and WHO Prequalification (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized CoPP before issuance of Registration letter.	
90.	Name, address of Applicant / Importer	**Vikor Enterprises** Plot # Z2-A, S.I,T.E. Manghopir Road , Karachi
	Details of Drug Sale License of importer	License No: 193 Address: Plot No. Z2-A, S.I.T.E. Manghopir Road Karachi Address of go-down: Plot F-24, S.I.T.E. Karachi Validity: 08-04-2023
	Name and address of marketing authorization holder (abroad)	Bharat Biotech International Limited Genome Valley, Shameerpet, Mandal, Medchal District- 500078, Telangana India.

	Name, address of manufacturer(s)	M/S Bharat Biotech International Limited, Genome Valley, Shameerpet, Mandal, Medchal District- 500078, Telangana India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original legalized COPP (No. 2117/STORES/2019-40) issued on 09-07-2019 by Drug Control Administration Government of Telangana India **valid upto 03-04-2022.** The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: Not less than once in a year)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization original legalized dated 18-06-2019 from Bharat Biotech International Limited. The letter specifies that the manufacturer exclusively authorized M/s Vikor Enterprises (Pvt) Ltd.Karachi to distribute, market , promote their mentioned products along with registration of the product in Pakistan..
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3915 dated 10-02-2022
	Details of fee submitted	Fee of Rs. 75,000/ dated 09-02-2022 Slip No. 61559468437
	The proposed proprietary name / brand name	**Rotavac** Rotavirus vaccine (live, oral) BP 2.5mL (Multidose) vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5ml (5 drops) contains: Vero cell derived Rotavirus 116E live Attenuated Bulk….. Not less than (NLT) $10^{5.0}$ FFU
	Dosage form of applied drug	Liquid in frozen form

	Pharmacotherapeutic Group of (API)	Live viral Vaccine
	Reference to Finished product specifications	BP Sepecification
	Proposed Pack size	2.5 ml Multi dose Vial
	Proposed unit price	Retail price: As per DPC
	Shelf Life	60 months
	Storage Conditions	-20 ^{O}C +5 ^{O}C
	The status in reference regulatory authorities	The product is WHO PQ as record available at WHO website accessed on 24th November, 2022. https://extranet.who.int/pqweb/content/rotavac-0
	For generic drugs (me-too status)	Rota virus in 5 dose is not registered as per available record.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance & drug product.
	Name, address of drug substance manufacturer	M/S Bharat Biotech International Limited, Genome Valley, Shameerpet, Mandal, Medchal District 500078, Talangana India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The real time stability data of Rotavirus 116E Live has conducted at -70 C +/-5C for 120 months and at -20 C +/-5C for 48 months. The accelerated stability studies conducted at +5 C +/- 3C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Analytical method validation/verification of product	Firm has submitted Analytical test method along with validation studies of the drug product.
	Container closure system of the drug product	Filled in 5 ml tubular glass vial having 20 mm neck of USP type I with 20 mm grey bromobutyl rubber stopper (RFU) sealed with 20 mm tear lift flip down (RFU) transparent violet colour seals.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions Rotavac 0.5 ml vial & 5 ml vial at -20 ^{O}C +5 ^{O}C for 60 months. And for the current presentation the firm has submitted stability study data for 36 months for 3 batches & for 60 months for two batches.
	Module-IV	The firm has submitted repeat dose toxicity study on Harlan Sprague Dawley Rats and New Zealand white rabbits.
	Module-V	i. Double blind Randomized Placebo controlled dose escalating Phase Ib/IIa Study to evaluate the safety and Immunogenicity of Live Attenated Rotavirus vaccine in Healthy Non Malnourished Infant 8-20 Weeks of Age. ii. A Phase III Randomized double blind placebo controlled trial to evaluate the protective efficacy of three doses of oral rotavirus vaccine (ORV) 116E, against severe rotavirus gastroenteritis in infants (**6799 Subjects**) iii. A Phase III Randomized double blind placebo controlled trial to evaluate the Non-interference in the Immune Response og three doses of oral rotavirus vaccine (ORV) 116E to Antigens contained in childhood vaccinre and to assess the clinical Lot Consistency of three production Lots.
	Remarks	a. CoPP is expired on **valid upto 03-04-2022** while was valid at the time of submission of the application. b. Real time stability study of two batches are submitted however as per ICH brackating study, the firm has submitted real time stability study data for lowest (0.5ml vial) & highest presenatation (5ml vial).
	Decision: Keeping in view legalized CoPP and WHO Prequalification (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm shall submit valid legalized CoPP before issuance of Registration letter.	
91.	Name, address of Applicant / Importer	**Vikor Enterprises** Plot # Z2-A, S. I, T. E. Manghopir Road , Karachi
	Details of Drug Sale License of importer	License No: 193 Address: Plot No. Z2-A, S.I.T.E. Manghopir Road Karachi Address of go-down: Plot F-24, S.I.T.E. Karachi Validity: 08-04-2023
	Name and address of marketing authorization holder (abroad)	Bharat Biotech International Limited Genome Valley, Shameerpet, Mandal, Medchal District- 500078, Telangana India.
	Name, address of manufacturer(s)	M/S Bharat Biotech International Limited, Genome Valley, Shameerpet, Mandal, Medchal District- 500078, Telangana India.

	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original legalized COPP (No. 2117/STORES/2019-40) issued on 09-07-2019 by Drug Control Administration Government of Telangana India **valid upto 03-04-2022.** The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection: Not less than once in a year)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization original legalized dated 18-06-2019 from Bharat Biotech International Limited. The letter specifies that the manufacturer exclusively authorized M/s Vikor Enterprises (Pvt) Ltd.Karachi to distribute, market , promote their mentioned products along with registration of the product in Pakistan..
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3914 dated 10-02-2022
	Details of fee submitted	Fee of Rs. 75,000/ dated 09-02-2022 Slip No. 275188604
	The proposed proprietary name / brand name	**Rotavac** Rotavirus vaccine (live, oral) BP 0.5mL (Single) vial
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose of 0.5ml (5 drops) contains: Vero cell derived Rotavirus 116E live Attenuated Bulk….. Not less than (NLT) $10^{5.0}$ FFU
	Dosage form of applied drug	Liquid in frozen form
	Pharmacotherapeutic Group of (API)	Live viral Vaccine

	Reference to Finished product specifications	BP Sepecification
	Proposed Pack size	0.5 ml Single dose Vial
	Proposed unit price	Retail price: As per DPC
	Shelf Life	60 months
	Storage Conditions	-20 C +/-5C
	The status in reference regulatory authorities	
	For generic drugs (me-too status)	Rotasil single dose by Hospital Sale & Services
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance & drug product.
	Name, address of drug substance manufacturer	M/S Bharat Biotech International Limited, Genome Valley, Shameerpet, Mandal, Medchal District 500078, Talangana India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The real time stability data of Rotavirus 116E Live has conducted at -70 C +/-5C for 120 months and at -20 C +/-5C for 48 months. The accelerated stability studies conducted at +5 C +/- 3C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted Analytical test method along with validation studies of the drug product.
	Container closure system of the drug product	Filled in 5 ml tubular glass vial having 20 mm neck of USP type I with 20 mm grey bromobutyl rubber stopper (RFU) sealed with 20 mm tear lift flip down (RFU) transparent violet colour seals.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches at real time conditions. The real time stability data is conducted at -20 ^{O}C +5 ^{O}C for 60 months. The accelerated stability data provided is of 03 batch and is conducted at at 5°C ± 3°C for 06 months.
	Module-IV	The firm has submitted repeat dose toxicity study on Harlan Sprague Dawley Rats and New Zealand white rabbits.
	Module-V	iv. Double blind Randomized Placebo controlled dose escalating Phase Ib/IIa Study to evaluate the safety and Immunogenicity of Live Attenated Rotavirus vaccine in Healthy Non Malnourished Infant 8-20 Weeks of Age. v. A Phase III Randomized double blind placebo controlled trial to evaluate the protective efficacy of three doses of oral rotavirus vaccine (ORV) 116E, against severe rotavirus gastroenteritis in infants (**6799 Subjects**) vi. A Phase III Randomized double blind placebo controlled trial to evaluate the Non-interference in the Immune Response og three doses of oral rotavirus vaccine (ORV) 116E to Antigens contained in childhood vaccinre and to assess the clinical Lot Consistency of three production Lots.
	Remarks	a. CoPP is expired on **valid upto 03-04-2022** while was valid at the time of submission of the application. b. The product is from India & not Prequalfied in the 0.5 ml single dose vial while the other two presenatation are WHO PQ.
	Decision: Registration Board approved the product and referred the case to DRAP Authority for seeking guidance regarding the importability of the product from India as per IPO being non WHO PQ product.	
92.	Name, address of Applicant / Importer	**M/s Roche Pakistan Limited,** 1st floor, 37-B, Block 6, PECHS, Karachi.
	Details of Drug Sale License of importer	License No: 0171 Address: Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi. Validity: 13-09-2024. Status: Drug License by way of wholesale and Drug License by way of retail sale
	Name and address of marketing authorization holder (abroad)	Genentech, Inc. (A member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080 Unites States of America
	Name, address of manufacturer(s)	F. Hoffmann-La Roche AG, Wurmisweg, Kaiseraugst 4303 Switzerland
	Name of exporting country	Switzerland

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Copy of BLA Approval Letter dated 28-05-2021, issued by USFDA indicating that the product is manufactured at M/s F. Hoffmann-La Roche Ltd, Kaiseraugst. Web link of official US FDA website for approval letter verification is given below: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm
	Details of letter of authorization / sole agency agreement	• Product specific authorization letter from M/s F. Hoffmann-La Roche Ltd., Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 12-04-2022 wherein the applicant has been authorized for marketing & distribution of the product in Pakistan. • Copy of letter indicating relationship between Genentech, Inc. (A member of the Roche Group) and M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.20209 dated 15th July, 2022
	Details of fee submitted	Deposit Slip no. 752867851401 PKR 75,000: Dated 15-06-2022
	The proposed proprietary name / brand name	Vabysmo
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Faricimab 6mg/0.05ml (120mg/mL) Each single dose vial contains: Faricimab…….6mg

	Dosage form of applied drug	Intravitreal use
	Pharmaco-therapeutic Group of (API)	Ophthalmological, other ocular vascular disorder agent. Humanized anti-VEGF-A and anti-Ang-2 bispecific Antibody VA2
	Reference to Finished product specifications	Innovator's specifications
	Proposed pack size	1's 2mL vial (Each glass vial contains an overfill amount to allow for administration of a single 0.05 mL dose of solution containing 6 mg of VABYSMO)
	Proposed unit price	As per SRO
	Shelf life	24 months
	Storage conditions	2°C - 8°C
	The status in reference regulatory authorities	The product is registered in USFDA
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Roche Diagnostics GmbH, Nonnenwald 2 , 82377 Penzberg, Germany.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification

		of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 18 months real time stability data at -40°C of 03 batches • 06 month accelerated stability data 5°C of 03 batches
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the data from the PPQ batches demonstrate that the FDC drug product manufacturing process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and that the in-process tests are suitable to monitor the manufacturing process.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	2 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless
	Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 5°C of 03 batches • 06 month accelerated stability data 25°C of 03 batches
	Module-IV Non-Clinical	4.2.1 Pharmacology 4.2.1.1 Primary Pharmacodynamics • NC 1056781. RO6867461: Affinity and cross reactivity of the CrossMab VEGF/Ang-2 IgG1 P329G LALA +AAA to its Ligands and Fc effector molecules (Amended) • NC 1056925. Efficacy of RO6867461 in the laser induced model of choroidal neovascularization in non-human. primate (including amendment no. 1) • NC 1103767. RO6867461: Effect of Anti-VEGF/ANG-2 (RG7716) Antibody in Laser Induced In Vivo Model of Choroidal Neovascularization 4.2.2 Pharmacokinetics 4.2.2.1 Analytical Methods and Validation Reports (if separate reports are available)

		• NC 1056820. Validation for the Determination of RO6867461 in Cynomolgus Monkey Serum by ELISA (including Addendum I and II) • NC 1056821. Anti-RO6867461 ELISA: Immunoassay Validation Report of a Bioanalytical Method for the Detection of Anti-RO6867461 Antibodies in Cynomolgus Monkey Serum by ELISA (including Addendum I and II) • NC 1056822. RO6867461 ELISA: Qualification Report for the Determination of RO6867461 in Cynomolgus Monkey Vitreous Humor by ELISA 4.2.2.2 Absorption • NC 1048699. RO6867488, RO6867461, and RO6892065: Pharmacokinetic assessment after intravenous administration to New Zealand white rabbits. November 2012 • NC 1048818. RO6867488 and RO6867461. Pilot Ocular Pharmacokinetic Study Following a Single Intravitreal Administration in Pigmented Rabbits • NC 1050473. RO6867461, RO6867488 and RO6892065: Pharmacokinetic assessment following intravitreal and intravenous administration to cynomolgus monkeys • NC 1053033. RO6867461: Sample Collection for the Determination of the Pharmacokinetic Distribution of RO6867461 Following Intravitreal Administration to Cynomolgus Monkeys, 2013 4.2.3 Toxicology 4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations) • NC 1053361. 2-Month Toxicity and Toxicokinetic Study with RO6867461 Following Intravitreous and Intravenous Administration in Cynomolgus Monkeys with a 4-Week Recovery Phase • NC 1053362. RO6867461: 2-Week Tolerance Study of RO6867461 Following Intravitreous and Intravenous Administration in Dutch-Belted Rabbits • NC 1053363. RO6867461: 2-Week Tolerance Study of RO6867461 Following Intravitreous and Intravenous Administration in Cynomolgus Monkeys • NC 1057630. RO6867461: 26-week partial ascending-dose toxicity and toxicokinetic study following once monthly intravitreous injections in cynomolgus monkeys with a 13-week recovery. July 2015. 4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluation) (If modified study designs are used, the following subheadings should be modified accordingly.) 4.2.3.5.2 Embryo-fetal development

		• NC 1093222. RO6867461: Intravenous administration embryo-fetal development study in the Cynomolgus monkey 4.2.3.7 Other Toxicity Studies (if available) 4.2.3.7.7 Other • NC 1055400. Evaluation of RO6867461 for the risk of cytokine release and immune cell depletion in an in vitro 24h-format Human Whole Blood Cell Assay (Amended) • NC 1055832. A Tissue Cross-Reactivity Study of RO6867461 in a Limited Panel of Normal Human Tissues • NC 1056445. A Tissue Cross-Reactivity Study of RO6867461 in Normal Human Tissues • NC 1059118. In vitro evaluation of RO6867461 in a Human Complement Activation Assay for the pre-clinical Risk Assessment of Anaphylatoxins and Complement split fragment generation • NC 1104409. Faricimab (RO6867461): Humanized anti-ANG-2 and anti-VEGF-A Bispecific Antibody, Carcinogenicity Assessment Document
	Module-V Clinical	A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab (RO6867461) in Patients with Neovascular Age-Related Macular Degeneration (nAMD). Primary CSR - Study GR40844, LUCERNE: A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab (RO6867461) in Patients with Neovascular Age-Related Macular Degeneration (nAMD). A Multiple-Center, Multiple-Dose And Regimen, Randomized, Active Comparator Controlled, Double Masked, Parallel Group, 36-Week Study To Investigate The Safety, Tolerability, Pharmacokinetics, And Efficacy Of RO6867461 Administered Intravitreally In Patients With Choroidal Neovascularization Secondary To Age-Related Macular Degeneration. Report No. 1083912. September 2018 A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab (RO6867461) in Patients with Diabetic Macular Edema. A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Diabetic Macular Edema. A Multiple-Center, Multiple-Dose, Randomized, Active Comparator-Controlled, Double-Masked, Parallel Group, 36-Week Study to Investigate the Safety,Tolerability,

		Pharmacokinetics, and Efficacy of RO6867461 Administered Intravitreally in Patients with Diabetic Macular Edema. A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab (RO6867461) in Patients with Diabetic Macular Edema.
Remarks of Evaluator: The firm has not submitted CoPP rather copy of Biologics license application (BLA) Approval Letter dated 28-05-2021, issued by indicating that the product is manufactured at M/s F. Hoffmann-La Roche Ltd, Kaiseraugst which is verifiable below mentioned link. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm Product specific authorization letter has been issued by M/s F. Hoffmann-La Roche Ltd., Basel Switzerland & the marketing authorization letter (BLA) issued by USFDA is for M/s Genentech, Inc. (A member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080 Unites States of America. For this purpose, that firm has submitted copy of letter indicating relationship between Genentech, Inc. (A member of the Roche Group) and M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland wherein it has been mentioned M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland is the operational headquarter company of the Roche group.		
Decision: Keeping in view the approval of USFDA Biologics license application (BLA), Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

93. Locally Manufactured Human Biological

The product HEPROX Injection Heparin Sodium 500 IU/ml; 5ml (Bovine Origin & Porcine Origin) along with other 19 products were applied by the firm for local manufacturing registration **on 7th March 2019** in the Pharmaceutical Evaluation Cell (PEC), PE&R division, DRAP on Form 5, when there was no requirement of Form-5F (CTD). However, **at that time the firm did not have Biological Section approval and Section approval was granted on 09-04-2020**. **The Biological Drugs Division received these applications on 15-09-2020 from PE&R Division.**
The guidance was sought from the Chairman Registration Board regarding the requirement of application on Form-5F (CTD) & it was communicated by the PE&R division duly endorsed by the Chairman RB wherein it was stated that registration Board considered such application if taken after its section approval.
The products are as under;

Sr.#	**Brand Name**	**Nature**
93.	EPTIN 2000 IU/ML Injection (Erythropoietin Alpha 2000 IU/ml)	r-DNA
94.	EPTIN 4000 IU/ML Injection (Erythropoietin Alpha 4000 IU/ml)	r-DNA
95.	EPTIN 10000 IU/ML Injection (Erythropoietin Alpha 10000 IU/ml)	r-DNA
96.	INOGEN Injection [Insulin Glargine 100 units/ml (3ml)]	r-DNA
97.	INOROX M Injection [70% Isophane Insulin Human and 30% Soluble Insulin Human 100 units/ml (10ml vial)]	r-DNA
98.	INOROX N Injection [Isophane Insulin Human 100 units/ml (10ml vial)]	r-DNA
99.	INOROX R Injection [Insulin Soluble Human 100 units/ml (10ml vial)]	r-DNA
100.	FILGET 300mcg/ml Injection (Filgrastim)	r-DNA

101.	PEG FILGET 6mg/0.6ml Injection (Pegfilgrastim 6mg/0.6ml)	r-DNA
102.	Ristop Injection (Rituximab 10mg/ml; (10ml vial & 50ml vial)	r-DNA
103.	ASTIN Injection (Bevacizumab 25mg/ml 4ml & 16ml)	r-DNA
104.	BOMIN 20% Injection (Albumin Human 2% (50ml Vial & 100ml Vial)	Non-rDNA
105.	V-NOM Injection (Polyvalent Anti Snake Venem Serum)	Non-rDNA
106.	HPT 10mcg Vaccine (Hepatitis B 10mcg/0.5ml Surface antigen adsorbed onto 0.25 Aluminium Hydroxide)	Non-rDNA
107.	Terox Vaccine (Tetanus Toxoid not less than 40IU Adsorbed Tetanus Vaccine)	Non-rDNA
108.	HPT 20mcg Vaccine (Hepatitis B 20mcg/1ml Surface antigen adsorbed onto 0.25 Aluminium Hydroxide)	Non-rDNA
109.	TYPHO Vaccine (Sammonella typhi 25mcg/0.5ml)	Non-rDNA
110.	GLOMIN 5% Injection (Human Immunoglobulin 5% (10ml Vial & 50ml Vial)	Non-rDNA
111.	HEPROX Injection Heparin Sodium 500 IU/ml; 5ml Bovine Origin	Non-rDNA
112.	HEPROX Injection Heparin Sodium 500 IU/ml; 5ml Porcine Origin	Non-rDNA

The products HEPROX Injection Heparin Sodium 500 IU/ml; 5ml (Bovine Origin & Porcine Origin) along with others non-rDNA product (formulation) are evaluated below as no requirements other than Form-5 is implemented for local manufacturing while the products at sr. no. 113-123 are rDNA in nature and Registration Board in its 297th meeting has approved the guidelines for local manufacturing and the data as per those guidelines are required to be submitted.

113.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	Formulation: M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000. Name of Bulk Manufacturer: 1. Hebei Changshan Biochemical Pharmaceutica Co., Ltd, China 2. Kin Master Produtos Quimicos Ltda, Brazil 3. Syntex S.A, Argentina
	Brand Name +Dosage Form + Strength	HEPROX Injection Injection 5000 IU/ ml (5ml vial)
	Composition	Each vial contains: Heparin sodium: 5000 IU/ ml (5ml vial) (Bovine origin)
	Finished product specifications	British Pharmacopoeia Specification (BP)

	Pharmacological Group	Anticoagulant
	Shelf life	03 Years (store below 25^0C)
	Products already registered in Pakistan	Multiparin
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 14285 (R&I) Dated 07-March-2019 Rs. 20,000/- 27-March-2019
	Demanded Price / Pack size	As per SRO Pack of 1's vial and Pack of 10's vials (5ml)
	General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
	Remarks of Evaluator	

114.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	Formulation: M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000. Name of Bulk Manufacturer: 1. Yantai Dongcheng Pharmaceutical Group Co., Ltd, China 2. Yino Pharma Limited, China 3. Hubei Enoray Biopharmaceutical Co., Ltd, China
	Brand Name +Dosage Form + Strength	HEPTOX Injection Injection 5000 IU/ ml (5ml vial)
	Composition	Each vial contains: Heparin Sodium : 5000 IU/ ml (5ml vial) (Porcine origin)
	Finished product specifications	British Pharmacopoeia Specification (BP)
	Pharmacological Group	Anticoagulant
	Shelf life	3 Years (store below 25^0C)

	Products already registered in Pakistan	Brand Name: Multiparin
	Type of Form	Form-5A
	Dy No & Date of application,	Dy. No. 14283 (R&I) Dated 07-March-2019
	Fee submitted	Rs. 20,000/- 06-March-2019
	Demanded Price / Pack size	As per SRO Pack of 1's vial & Pack of 10's vials (5ml)
	General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
	Remarks of Evaluator	i.
115.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	Ready to Fill: M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000. Name of Bulk Manufacturer (Ready to Fill): PT BIOFARMA, Indonesia
	Brand Name +Dosage Form + Strength	HPT Vaccine Injection 10mcg/ 0.5ml
	Composition	Each vial contains: Hepatitis B : 10mcg Surface antigen adsored onto 0.25mg aluminium hydroxide
	Finished product specifications	British Pharmacopoeia Specification (BP)
	Pharmacological Group	Immunoglobulin
	Shelf life	3 Years (store between 2-8^{0}C)
	Products already registered in Pakistan	Brand name: Amvax B Registration Holder: M/s Amson Vaccines Pharma, Islamabad
	Type of Form	Form-5A
	Dy No & Date of application,	Dy. No. 14293 (R&I) Dated 07-March-2019

	Fee submitted	Rs. 20,000/- 06-March-2019
	Demanded Price / Pack size	As per SRO Pack of 1's vial x 0.5ml & 10's vials x 0.5ml
	General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
	Remarks of Evaluator	i.
116.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	Ready to Fill: M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000. Name of Bulk Manufacturer: PT BIOFARMA, Indonesia
	Brand Name +Dosage Form + Strength	V-NOM Vaccine Liquid Injection 10ml Ampoule
	Composition	Each ml contains: Standard Cobra Venom (Naja naja) : 0.6mg Standard Common Krait Venom (Bungaruscaeruleus) : 0.45mg Standard Russell's Viper Venom (Viperarusselli) : 0.6mg Standard Sawscaled Viper Venom (Echisarinatus) : 0.45mg
	Finished product specifications	Manufacturer Specifications
	Pharmacological Group	Immunoglobulin
	Shelf life	3 Years (store between 2-8^{0}C)
	Products already registered in Pakistan	Brand name: ASVs Registration Holder: M/s Amson Vaccines Pharma, Islamabad
	Type of Form	Form-5A
	Dy No & Date of application,	Dy. No. 14259 (R&I) Dated 07-March-2019
	Fee submitted	Rs. 20,000/- 06-March-2019
	Demanded Price / Pack size	As per SRO Pack of 1's ampoule (10ml)

	General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
	Remarks of Evaluator	i.
117.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	Brand Name +Dosage Form + Strength	HPT 20mcg Vaccine Injection 20mcg
	Composition	Each ml contains: Hepatitis B : 20mcg Surface antigen adsorbed onto 0.5mg aluminium hydroxide
	Finished product specifications	British Pharmacopoeia Specification (BP)
	Pharmacological Group	Immunoglobulin
	Shelf life	3 Years (store between 2-8^{0}C)
	Products already registered in Pakistan	Brand name: Amvax B Registration Holder: M/s Amson Vaccines Pharma, Islamabad
	Type of Form	Form-5A
	Dy No & Date of application,	Dy. No. 14291 (R&I) Dated 07-March-2019
	Fee submitted	Rs. 20,000/- 06-March-2019
	Demanded Price / Pack size	As per SRO Pack of 1's amp x 1ml & 10's amp x 1ml
	General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
	Remarks of Evaluator	i.

118.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	Brand Name +Dosage Form + Strength	Terox Vaccine Injection 40mcg
	Composition	Each dose of 0.5ml contains: Tetanus Toxoid : ≥ 40 IU
	Finished product specifications	British Pharmacopoeia Specification (BP)
	Pharmacological Group	Monoclonal antibody
	Shelf life	3 Years (store between 2-8^{0}C)
	Products already registered in Pakistan	Brand name: Imatet Registration Holder: M/s Amson Vaccines Pharma, Islambad
	Type of Form	Form-5A
	Dy No & Date of application,	Dy. No. 14287 (R&I) Dated 07-March-2019
	Fee submitted	Rs. 20,000/- 06-March-2019
	Demanded Price / Pack size	As per SRO Pack of 1's amp x 1ml & 10's amp x 1ml
	General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
	Remarks of Evaluator	i.
119.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.

	Brand Name +Dosage Form + Strength	BOMIN Injection Injection 50ml vial & 100ml vial
	Composition	Each vial contains: Human Albumin : 20% (50ml vial & 100ml vial)
	Finished product specifications	USP Specification
	Pharmacological Group	Blood Derivative
	Shelf life	3 Years (store below 25^0C)
	Products already registered in Pakistan	Brand name: Albutein Registration Holder: M/s S. Ejazuddin, Karachi
	Type of Form	Form-5A
	Dy No & Date of application,	Dy. No. 14274 (R&I) Dated 07-March-2019
	Fee submitted	Rs. 20,000/- 06-March-2019
	Demanded Price / Pack size	As per SRO Pack of 1x50ml vial & 1x100ml vial
	General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
	Remarks of Evaluator	
120.	Name of Importer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	DSL details	DML No: 000651 GMP valid upto: 16th March, 2018 Place: Islamabad
	Name of Manufacturer	M/s Rotex Pharma Pvt Ltd. Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad – Pakistan. Post Code 44000.
	Brand Name +Dosage Form + Strength	GLOMIN Injection Injection 1x10ml vial & 1 x 50ml vial
	Composition	Each vial contains: Human Immunoglobulin : 5% (10ml vial & 50ml vial)
	Finished product specifications	USP Specification
	Pharmacological Group	Immunoglobulin
	Shelf life	3 Years (store below 25^0C)

Products already registered in Pakistan	Brand name: Gammaraas Registration Holder: M/s Popular International, Karachi
Type of Form	Form-5A
Dy No & Date of application,	Dy. No. 14284 (R&I) Dated 07-March-2019
Fee submitted	Rs. 20,000/- 06-March-2019
Demanded Price / Pack size	As per SRO Pack of 1x10ml vial & 1x100ml vial
General documentation	The firm has approval of following biological sections from Central Licensing Board: Biotech rDNA Vial Section (Formulation, filling and sealing) Biological- Non-rDNA Vial Section (Formulation, filling and sealing) Biological- Vaccines Ampoule filling & Sealing (Ready to Fill Form) Quality Control (Revised)
Remarks of Evaluator	

Decision: Registration Board advised to evaluate all such cases for which the required section is available at the time of evaluation. The Board advised the firm to submit the following data:

For non-rDNA products:

a) Nature of the bulk being imported (Ready-to-fill or Bulk Concentrate).
b) 6 months accelerated and real time stability studies for drug substance from exporting country.
c) Certificate of Analysis (performed by bulk manufacturer) of finished product being manufactured from same bulk.
d) The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform analytical studies as detailed in Certificate of Analysis or as per Pharmacopoeia monograph in case of Pharmacopoeial products.
e) The local manufacturer shall provide the product development and accelerated and real time stability study data of 3 batches for 6 months of drug product manufactured locally.

For rDNA products:

a) Data in light of guidelines for locally manufactured r-DNA therapeutic proteins approved in 297th meeting of Registration Board.

Miscellaneous/ Deferred Cases:

The following product was deferred in 285th meeting of Registration Board as per following details.

121.	Name of Importer	M/s Sindh Medical Store, Sector 13B/B-10 Block-6 PECHS Karachi.
	DSL details	Copy of DSL No. 0160dated 02-07-2016 valid till 01-07-2018. The firm has submitted the copy of renewal fee challan of Rs. 5000/- dated 27-06-2018
	Name of Manufacturer	M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet Mandal, Medchal District- 500 078, Telangana State, India.

Brand Name	Rotavac
+Dosage Form + Strength	Rotavirus Vaccine (Live, Oral) BP
Composition	Each dose of 0.5mL (5 drops) contains: Vero cell derived Rotavirus 116E Bulk, Live Attenuated……..NLT $10^{5.0}$ FFU
Finished product specifications	BP Specification
Pharmacological Group	Live viral vaccine
Shelf life	60 months at -20^0C
Products already registered in Pakistan	
Type of Form	Form 5-A
Dy No & Date of application, Fee submitted	Dy No. 1254(R&I) Date: 03-03-2016. Rs. 100,000/- dated 02-03-2016
Demanded Price / Pack size	1's Vial (2.5ml)/ Not Provided

The product was deferred in 285th meeting of RB & the Board decided as under;
Registration Board deferred the product for following by the firm:
a. Confirmation of sole agency agreement.
b. Submission of complete data of real time and accelerated stability studies of three (03) batches.

The firm has not provided the required sole agency agreement till date & M/s Vikor entreprise Karachi has applied for registration of the products long with submission of product specific letter of authorization original legalized dated 18-06-2019 from Bharat Biotech International Limited The letter specifies that the manufacturer exclusively authorized M/s Vikor Enterprises (Pvt) Ltd. Karachi to distribute, market , promote their mentioned products along with registration of the product in Pakistan.

Decision: Registration Board rejected the application as firm does not have valid Authorization/ sole agency agreement for the said product.

Deferred case of Nivolunix 40mg Injection applied by M/s Himmel Pharmaceuticals (Pvt) Ltd Lahore.

The following products of M/s Himmel Pharmaceuticals (pvt) Ltd Lahore was deferred in 320th meeting of Registration Board as per following details.

122.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-0016174D **Address:** 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan **Address of go-down: N/A** **Validity: 06-02-2022** **Status:** License to sell drugs by way of Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited **Plant address**: Kathali Bhaluka Mymensingh **Bangladesh.** **Office Address**: 9/B/2 Toyenbee Circular Road Motijheel, Dhaka 1223 Bangladesh

	Name, address of manufacturer(s)	-do-
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3355) issued on 4-June-2020 **by** Directorate General of Drug Administration Ministry of Health & Family welfare Government of the people's republic of Bangladesh. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:2years)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization dated 02-06-2020 from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register & sell their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No32920 Dated 10.12.2020, Dy. No.8733 Dated 05.04.2022, Dy. No.13612 Dated 06.06.2022
	Details of fee submitted	Rs. /- 50000 Dated 19.11.2020
	The proposed proprietary name / brand name	Nivolunix 40 Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains Nivolumab INN….40mg
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agents (Anti-cancer), Monoclonal Antibodies
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack Size: 1's
	Proposed unit price	Retail price As per SRO

	Shelf Life	24 months
	Storage Conditions	2 ^{O}C -8^{O}C
	The status in reference regulatory authorities	OPDIVO (NIVOLUMAB 40mg/4mL single dose vial) | BLA #125554 | BRISTOL MYERS SQUIBB in USFDA
	For generic drugs (me-too status)	Not available in Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at 25±2°C for 10 days, at 5 ±3 °C for 6months & ≤-30 °C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted specification & in-house analytical method along with Analytical method validation studies for the applied product.
	Container closure system of the drug product	Nivolunix 40mg injection is provided in 5mL clear glass vial (USP type-I glass) 20 mm rubber stopper, type -1 and 20 mm Flip off seal with red color top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 commercial batches. The accelerated stability study data is conducted at 40° C ± 2° C & 75% ± 5% RH for 6 months. The real

		time stability study data is conducted at 2 ^{O}C -8^{O}C for 24 months.
	Module-IV	**Pharmacology studies:** The binding of product to human CD279 (programmed cell death 1, PD-1): • Effects on interaction between PD-1 and PD-1 ligands using the PD-1/CHO cell line and biotin-labeled recombinant human PD-L1- Fc and PD-L2-Fc fusion proteins. • Effect on immunoreactivity (on alloantigen-induced T-cell activation, antigen-specific T cell reactivity using Cynomolgus monkeys) • Activity against malignant tumors in mice with malignant melanoma B16F10 cells. • Secondary pharmacodynamics (antibody-dependent cell-mediated cytotoxicity) • Safety pharmacology (Effects on the central nervous system, Effects on the cardiovascular system, Effects on the respiratory system) **Pharmacokinetic studies:** (Analytical procedures-assay, antibody assay, Single-dose administration, Repeated-dose administration) **Toxicology studies:** Single-dose toxicity using cynomolgus monkeys, Repeated-dose toxicity in cynomolgus monkeys, Extended study of pre- and postnatal development in cynomolgus monkeys, Cross-reactivity studies, Four-week repeated intravenous dose toxicity study with ipilimumab coadministration in cynomolgus monkeys) **Note:** The submitted clinical trial data is from bulk manufacture not from the finish product manufacter.
	Module-V	**Phase I study:** • An open-label study to investigate the pharmacokinetics (PK) in 17 patients with advanced solid tumors resistant to conventional therapies. **Phase II study:** An open-label study to investigate the PK and other endpoints in 35 patients. **Phase III study:** A Phase III trial to compare the efficacy & safety of FX02 and Opidivo (Nivolumab) injection in patients with advance NSCLC who had received prior platinum-based chemotherapy. **Note:** The submitted clinical trial data is from bulk manufacture not from the finish product manufacturer.
123.	Name, address of Applicant / Importer	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan Address of go-down: N/A

		Validity: 06-02-2022 Status: License to sell drugs by way of Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh. Office Address: 9/B/2 Toyenbee Circular Road Motijheel, Dhaka 1223 Bangladesh
	Name, address of manufacturer(s)	-do-
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original legalized COPP (DA/6-110/2016/3355) issued on 4-June-2020 by Directorate General of Drug Administration Ministry of Health & Family welfare Government of the people's republic of Bangladesh. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:2years)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization dated 02-06-2020 from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register & sell their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No32921 Dated 10.12.2020, Dy. No.8733 Dated 05.04.2022, Dy. No.13612 Dated 06.06.2022
	Details of fee submitted	Rs. /- 50000 Dated 19.11.2020
	The proposed proprietary name / brand name	**Nivolunix 100 Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains Nivolumab INN….100mg
	Dosage form of applied drug	Injection

	Pharmacotherapeutic Group of (API)	Antineoplastic agents (Anti-cancer), Monoclonal Antibodies
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack Size: 1's
	Proposed unit price	Retail price As per SRO
	Shelf Life	24 months
	Storage Conditions	2^0C -8^0C
	The status in reference regulatory authorities	OPDIVO (NIVOLUMAB 100mg single dose vial) | BLA #125554 | BRISTOL MYERS SQUIBB in USFDA
	For generic drugs (me-too status)	Not available in Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at 25±2 °C for 10 days, at 5 ±3 °C for 6months & ≤-30 °C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted specification & in-house analytical method along with Analytical method validation studies for the applied product.

	Container closure system of the drug product	Nivolunix 40mg injection is provided in 5mL clear glass vial (USP type-I glass) 20 mm rubber stopper, type -1 and 20 mm Flip off seal with red color top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 commercial batches. The accelerated stability study data is conducted at 40° C ± 2° C & 75% ± 5% RH for 6 months. The real time stability study data is conducted at 2 OC -8OC for 24 months.
	Module-IV	Pharmacology studies: The binding of product to human CD279 (programmed cell death 1, PD-1): • Effects on interaction between PD-1 and PD-1 ligands using the PD-1/CHO cell line and biotin-labeled recombinant human PD-L1- Fc and PD-L2-Fc fusion proteins. • Effect on immunoreactivity (on alloantigen-induced T-cell activation, antigen-specific T cell reactivity using Cynomolgus monkeys) • Activity against malignant tumors in mice with malignant melanoma B16F10 cells. • Secondary pharmacodynamics (antibody-dependent cell-mediated cytotoxicity) • Safety pharmacology (Effects on the central nervous system, Effects on the cardiovascular system, Effects on the respiratory system) Pharmacokinetic studies: (Analytical procedures-assay, antibody assay, Single-dose administration, Repeated-dose administration) Toxicology studies: Single-dose toxicity using cynomolgus monkeys, Repeated-dose toxicity in cynomolgus monkeys, Extended study of pre- and postnatal development in cynomolgus monkeys, Cross-reactivity studies, Four-week repeated intravenous dose toxicity study with ipilimumab coadministration in cynomolgus monkeys) Note: The submitted clinical trial data is from bulk manufacture not from the finish product manufacter.
	Module-V	Phase I study: • An open-label study to investigate the pharmacokinetics (PK) in 17 patients with advanced solid tumors resistant to conventional therapies. Phase II study: An open-label study to investigate the PK and other endpoints in 35 patients. Phase III study: A Phase III trial to compare the efficacy & safety of FX02 and Opidivo (Nivolumab) injection in patients with advance NSCLC who had received prior platinum-based chemotherapy.

		Note: **The submitted clinical trial data is from bulk manufacturer not from the finish product manufacturer.**

Bio-similarity studies:	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	**Primary Structure:** Amino acid sequence by LC-MS & MS/MS N-terminal sequence by LC-MS. C-terminal lysine by LC-MS. N-glycosylation site by Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) **Secondary Structure & high order Structure** Intact mass by LC-MS Disulfide bond by LC-MS Free thiol (Ellman's) Circular Dichroism (Secondary Structure) by Far spectrogram. Thermostability by differential fluorimetry (DSF) **Heterogenicity** Glycan by LC-MS Heterogenicity of glycosylation by FLD-HPLC Isoelectric point by CIEF Charge variant (CEX-HPLC
Biological Activity	Biological activity by: PD-I binding activity by ELISA
Impurities	Purity by SEC-HPLC Purity by CE-SDS Protein A by ELISA DNA residual by qPCR Host cell protein by ELISA
Stability Studies	Stability studies are provided.
Non-clinical Studies	Primary pharmacodynamics by: Binding to PD-I Inhibitory effect against binding of PD-I to PD-L1 or PD-L2 One month repeated doses toxicity study in monkeys Six months repeated doses toxicity study in monkeys
Clinical Studies	Comparative clinical study has not been submitted.

Registration board in it 320th meeting deferred the case as per following details.

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

Clarification of label claim (composition).

Comparative clinical trial data with innovator drug.

Regulatory Guidelines of country of origin (Bangladesh) indicating that the registration of above products was granted in exporting country on the basis of non-clinical & clinical trial data of bulk manufacturer of China.

The firm has submitted new legalized CoPP wherein the label claim (composition) was corrected (from "Formulated bulk of Nivolumab INN" to "Nivolumab INN".

The submitted data (non-clinical, clinical etc.) is from bulk manufacture not from the finish product manufacturer for this purpose the firm has submitted guidelines of the country of origin

(Bangladesh) wherein it has been mentioned in Annexure 1 that clinical trial report from bulk manufacturer may also be submitted instead of clinical trial report conducted in Bangladesh.
Decision: Registration Board deferred the case to confirm the relevant guidelines and regulatory (free sale) status of the finished product manufactured by the same bulk in China.

Imported Human Biologicals applied by M/s Punjab Medical Services, Lahore approved in 312th meeting of Registration Board.

Following product of M/s Punjab Medical Services, Lahore was approved in 312th meeting of Registration Board as per following details:

124.	**Name, address of Applicant / Importer**	**M/s Punjab Medical Services, Office No. 4/5, Jalal Center, Opposite O.P.D. Gate Sir Ganga Ram Hospital, Mozang Road, Lahore.**
	Details of Drug Sale License of importer	**License No:** 05-352-0063-041061D **Address:** Office No. 4/5, Jalal Center, Opposite O.P.D. Gate Sir Ganga Ram Hospital, Mozang Road, Lahore. **Address of go-down:** Office No. 4/5, Jalal Center, Opposite O.P.D. Gate Sir Ganga Ram Hospital, Mozang Road, Lahore. **Validity: 27-02-2023** **Status:** License to sell drugs as a distributor .
	Name and address of marketing authorization holder (abroad)	M/s KocselIlac Sanayi ve Tic. A.S. Kosuyolu Cad No: 34, 34718 Kosuyolu, Kadikoy, Istanbul, Turkey.
	Name, address of manufacturer(s)	M/s OncoIlac Sanayi ve Tic. A.S. Gebze Organize Sanayi Bolgesi, 1700 Sokak, No: 1703 Gebze, Kocaeli, Turkey.
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** • Firm has submitted legalized CoPP (No. 2018/1150) dated 22-03-2018valid till 22-03-2020. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of letter of authorization from General Director of *KoçselİlaçSan ve. Tic. A.Ş.* According to the letter, the firm *M/s KocselIlac Sanayi ve Tic. A.S., Kosuyolu Cad No: 34, 34718 Kosuyolu, Kadikoy, Istanbul, Turkey* authorizes "*M/s Punjab Medical Services*" to perform the registration procedures, sales and other similar activities concerning medicinal products for territory of Pakistan. The letter was issued on 16-07-2019 valid till 31-07-2021. The appendix 1 of the letter of authorization contains products list containing Pamintu 10mg.
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No. 1946 (R&I) & 4720 (R&I) dated 19-02-2020 & 11-02-2021.
	Details of fee submitted	Rs.100,000/- dated 10-02-2020.
	The proposed proprietary name / brand name	**Pamintu 10mg/ml** **Solution for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Protamine Sulfate..……10mg
	Dosage form of applied drug	Suspension for Injection
	Pharmacotherapeutic Group of (API)	Antidote
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's Vial (5mL)
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Below 30^0C
	The status in reference regulatory authorities	Prosulf® 10mg/ml Solution for Injection
	For generic drugs (me-too status)	Protamine Sulphate of CP Pharma.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO Template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Alps Pharmaceuticals Ind. Co.,Ltd. 10-50, Furukawacho Mukaimachi Nichome, Hida, Gifu, 5009-4241, Japan.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities,

		physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at real time and accelerated conditions. The real time stability data is conducted at 25ºC ± 2ºC, 60% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the Assay Analytical Method Validation, Related Compound Method Analytical Method Validation, Bacterial Endotoxin Method Validation and Sterility Method Validation are performed for Pamintu 10 mg/mL Solution for Injection.
	Container closure system of the drug product	• Pamintu 10 mg/mL Solution for Injection as 50 mg/5 mL is placed in 5 mL sterile Type I neutral glass vial and 20 mm bromobutyl rubber stopper and 20 mm flip tear off seal. Vials are presented with instructions for use in a cardboard box.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted real time stability study data of 3 batches at 30°C±2°C %65RH±%5RH for 30 months. The accelerated stability study data is conducted at 40°C±2°C %75RH±%5RH for 6 months for 03 batches.
	Module-IV Non-Clinical	Not Performed
	Module-V Clinical	Not Performed.

Last Decision of RB:

Keeping in view the shortage of product and public health need, Registration Board approved the product as per valid legalized CoPP and current import policy for finished drugs. The firm shall submit following documents before issuance of registration letter and Chairman Registration Board is authorized for issuance:

Periodic Safety Update Report of last 03 years of the product from country of origin.

Certificate of Analysis of 03 consecutive batches from country of origin.

Guidelines of country of origin on the basis of which product was approved.

The Board further decided that the said decision is only applicable to instant case to ensure the availability of product for needy patients and shall not be applicable to any other case.

In light of above decision of the Board, the firm has submitted the following documents:

i. Periodic Benefit Risk Evaluation Report from 28-04-2016 to 28-11-2020 which indicates that 595118 boxes were sold during reporting period and concluded that there is nothing to change the benefit-risk balance in the reporting interval and the benefit-risk profile of the product remains useful in its approved indication.
ii. Certificates of Analysis of 03 batches and clarification regarding consecutive batches.
iii. For guidelines, the firm has submitted that Turkish Health Authority follows European Guidelines as indicated in Turkish Marketing Authorization Regulation dated **19-01-2005**.

However, there is no such information on the marketing authorization certificate of Pamintu 10mg/ml dated **28-04-2016**.

The case was taken in 316th meeting of Registration board & the Board decided as under;

"Registration Board advised DBE&R to write an email to Turkish Medicine Agency to confirm the applicability of clinical trial data for registration of Pamintu 10mg/ml (Protamine Sulfate) in Turkey."

The email was sent accordingly & the following reply has been received through email addressed to Mr Zubair Masood Assistant Director (zubair.masood@dra.gov.pk) which is reproduced as under ;

"*Information about the product you requested from Turkish Medicines and Medical Devices Agency is shared with your side below.*

It has been seen that the product named "Pamintu 10 mg/ml Vial Containing Solution for Injection", which Drug Regulatory Authority of Pakistanrequested information about the marketing authorization process, is ***a generic product.***

Definition of generic medicinal product in Article 4 (i) of the Regulation on the Marketing Authorization of Medicinal Products for Human Use published in the Official Gazette dated 11 December 2021 is as follows:

*"****Generic medicinal product:*** *A medicinal product that has the same qualitative and quantitative composition and the same pharmaceutical form as the reference medicinal product in terms of active substance(s) and whose bioequivalence has been proven by appropriate bioavailability studies (Different salts, esters, ethers, isomers, isomer mixtures of an active substance, its complexes or derivatives are considered the same as the active substance unless their properties differ significantly in terms of safety or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance shall be submitted by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. The applicant does not need to submit bioavailability studies if he/she fulfils the relevant criteria as detailed in the guidelines for the generic medicinal product."*

Regarding the information and documents required to be submitted in the marketing authorization application in the same regulation the following provision is present,

"Informed consent application, established medical use application, allergen product application, generic medicinal product application, hybrid application, biosimilar medicinal product application, fixed combination application

ARTICLE 9 – (1) Save for the provisions of the Industrial Property Law dated 22/12/2016 and numbered 6769;

a) The applicant shall not be required to provide the results of toxicological and pharmacological tests and clinical trials provided that the he proves one of the following:

4) In the case of a generic medicinal product application to be made in the event that the medicinal product for human use for which the marketing authorisation application has been made, is basically similar to a reference medicinal product that has been authorised in accordance with the current legislative provisions and its data exclusivity period has expired."

In accordance with the Regulation on the Marketing Authorisation of Medicinal Products for Human Use, ***clinical trial results have not been sought in accordance with the European Union in the marketing authorisation application for the product in question.***

There are clinical data in the form of literature in the marketing authorization dossier."

It is clear from the email that the product under discussion Pamintu 10mg/ml (Protamine Sulfate) has been registered as a generic product in the country of origin & clinical trial is not required for generic product as per ARTICLE 9 – (1) as mentioned in the above email.

Decision: Keeping in view position narrated above, Registration Board approved the product as per valid legalized CoPP and current import policy for finished drugs.

125. Imported Human Biological applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pakistan Limited, Karachi has applied Quadrivalent Seasonal Influenza vaccine **having strains of Southern Hemisphere for grant of registration for Hajj Tender Purpose only**. The details of the applications are as follows:

Name of Manufacturer	**Name of Product**	**Pack Size**	**Document Details**	**Dy. No. Date of Application**
PLH: M/s Sanofi Pasteur, 14 Espace Henry Vallee 69007 Lyon, France. **Manufacturer:** M/s Sanofi Pasteur, Parc Industriel d'Incarville 27100, Val de Reuil, France	Vaxigrip Tetra Suspension for Injection in pre-filled syringe, quadrivalent influenza Vaccine (split virion, inactivated)-SH strains	1's PFS	Copy of CoPP No. 044853 dated 02-11-2021.	Dy. No. 33078 dated 17-12-2021 Rs. 75000/- dated 03-12-2021

The firm has submitted that WHO recommends strains for Northern Hemisphere in February and for Southern Hemisphere in September. It takes almost 6-8 months to produce and approve the full global supply of influenza vaccines. Shelf life of Flu vaccine is 12 months and NH 2021 strains that were recommended in February 2021 by WHO will not be available because it will be near expiry/ expired or consumed during Hajj season and new NH strains will not be available before Sept-Oct 2021. The firm further submitted the following recommendation of Ministry of Health of Saudi Arabia:
"Travelers arriving for Umrah, Hajj or for seasonal work in Hajj areas are recommended to get vaccinated against seasonal influenza.
Influenza vaccination is particularly important for pregnant women, children under 5 years, the elderly, and individuals with underlying health conditions (such as chronic cardiac, pulmonary, renal, metabolic, neurodevelopmental, liver or hematologic diseases) and individuals with immunosuppressive conditions (such as HIV/AIDS, receiving chemotherapy or steroids, or malignancy).

Therefore, if SH strains vaccine is not secured by us, we will be left without any choice for our pilgrims.

i. The copy of CoPP submitted indicates that the product is not subject to Market Authorization in country of origin as France is in Northern Hemisphere and the said product is for Southern Hemisphere.
ii. WHO recommends strains of seasonal influenza vaccines each year depending upon the circulating strains. Neither Pakistan nor Saudi Arabia is in Southern Hemisphere.

It is pertinent to mention that WHO recommends strains for Northern Hemisphere in February and as per firm's claim, it takes 6-8 months for manufacturing which means that the vaccine will be ready till August-October. Moreover, the shelf life of flu vaccine is 12 months. Hence, the product shall be valid till August-October. The Hajj 2022 is going to be held in start of July, hence, the vaccines of Northern Hemisphere shall not be expired at that time.

The case was taken in 316th meeting of Registration board & the Board decided as under;
Registration Board advised the firm to submit scientific justification of using Southern Hemisphere strains in Pakistan.

Now the firm has submitted that WHO recommended strains for year 2022-23 is same for both Northern Hemisphere **& Southern Hemisphere as reproduced**

- **an A/Victoria/2570/2019 (H1N1)pdm09-like virus;**
- **an A/Darwin/9/2021 (H3N2)-like virus;**

- **a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and**
- **a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.**

The firm requested to consider their request and register Vaxigrip Tetra (SH strains) for Hajj tender purpose only**,** so that Flu vaccine can be available for the Pakistani pilgrims going for hajj in upcoming year without any hinderance.

Remarsk of Evaluater: It is submitted the WHO recommended strain for southern hemisphere released in September, 2022 are changed from that of WHO recommended strains for year 2022-23 for Northern Hemisphere. The both are reproduced as under;

WHO recommends that quadrivalent vaccines for use in the 2023 **southern hemisphere influenza** season contain the following:

- an A/Sydney/5/2021 (H1N1)pdm09-like virus;
- an A/Darwin/9/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

WHO recommended strains for year 2022-23 for **Northern Hemisphere.**

- an A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- an A/Darwin/9/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

Decision: Registration Board advised to seek comments from CDC NIH regarding the request of the firm.

Cases of AD-III (Ms. Haleema Sharif)

126.	**Name and address of Importer**	**M/s Saadat International** 117 Habitat Flat Shadman II, Jail Road, Lahore
	Detail of DSL	M/s Saadat International Address: 117 Habitat Flat Shadman II, Jail Road, District Lahore Valid till: 12-Jun-2022
	Name and address of Manufacturer	**Marketing Authorization Holder:** M/s Boehringer Ingelheim Vetmedica GmbH Binger Strabe 173, 55216 Ingelheim am Rhein, Germany. **Manufacturer:** M/s Boehringer Ingelheim Animal Health Inc. USA Address: 1168 Airport Parkway, sw, Gainesville– GA. USA
	Name of exporting country	USA
	Brand Name +Dosage Form + Strength	Vaxxitek HVT +IBD+ND
	Diary No. Date of R& I & fee	Dy. No. 31554R&I Dated 16-11-2021 Rs. 150,000/- (Slip No. 38351268)
	Composition	Each dose contains: SR3 MDV vector expressing NDV antigen and IBD antigen: vHVT310, atleast… 5,696 pfu
	Pharmacological Group	Immunological, Q101AD16
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	18months (store in liquid nitrogen container) Stability studies of three batches at (2^0C-8^0C) for 30months.

	Document Details	• Original legalized certificate of Licensing and Inspection (No. 21-01306) dated March 02, 2021 is submitted by the firm. • Product specific letter of authorization is submitted by the firm.
	Pack size	2000 doses.
	Reference Regulatory Authority Availability	Approved in USA
	Products already registered in Pakistan	Innovax-ND (Marek's Disease - Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector) Turkey Herpesvirus (HVT): minimum of 1810 PFU/dose throughout dating Newcastle Disease Virus- Fusion (F) Protein: minimum of 1802 PFU/dose throughout dating
	Remarks of Evaluator	i. Composition of applied drug as per form 5A is ***SR3 MDV vector expressing NDV antigen and IBD antigen: vHVT310, atleast 5,696 pfu*** however on certificate and licensing and inspection it is ***Bursal Disease-Marek's disease new castle disease vaccine live marek's disease vector.*** Clarification for this difference is required moreover What does vHVT310 stands for? *Firm has submitted that all three designations have been used by different organization to refer to the same vaccine* • *Bursal Disease-Marek disease Newcastle disease vaccine live Marek's disease vector.* • *SR3 MDV vector expressing NDV antigen and IBD antigen.* • *vHVT310.*
	Decision: Approved as per Innovator's Specification and as per import policy for finished product.	
127.	**Name and address of Importer**	**M/s Saadat International** 117 Habitat Flat Shadman II, Jail Road, Lahore
	Detail of DSL	M/s Saadat International Address: 117 Habitat Flat Shadman II, Jail Road, District Lahore Valid till: 12-Jun-2022
	Name and address of Manufacturer	**Marketing Authorization Holder:** M/s Boehringer Ingelheim Vetmedica GmbH Binger Strabe 173, 55216 Ingelheim am Rhein, Germany. **Manufacturer:** M/s Boehringer Ingelheim Animal Health Inc. USA Address: 1168 Airport Parkway, sw, Gainesville– GA. USA
	Name of exporting country	USA

	Brand Name +Dosage Form + Strength	Vaxxitek HVT +IBD+ND
	Diary No. Date of R& I & fee	Dy. No. 1317R&I Dated 14-01-2022 Rs. 150,000/- (Slip No. 38351268)
	Composition	Each dose contains: SR3 MDV vector expressing NDV antigen and IBD antigen: vHVT310, atleast… 5,696 pfu
	Pharmacological Group	Immunological, Q101AD16
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	18months (store in liquid nitrogen container) Stability studies of three batches at (2^0C-8^0C) for 30months.
	Document Details	• Original legalized certificate of Licensing and Inspection (No. 21-01306) dated March 02, 2021 is submitted by the firm. • Product specific letter of authorization is submitted by the firm.
	Pack size	4000 doses.
	Reference Regulatory Authority Availability	Approved in USA
	Products already registered in Pakistan	Innovax-ND (Marek's Disease - Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector) Turkey Herpesvirus (HVT): minimum of 1810 PFU/dose throughout dating Newcastle Disease Virus- Fusion (F) Protein: minimum of 1802 PFU/dose throughout dating
	Remarks of Evaluator	i. Composition of applied drug as per form 5A is ***SR3 MDV vector expressing NDV antigen and IBD antigen: vHVT310, atleast 5,696 pfu*** however on certificate and licensing and inspection it is ***Bursal Disease-Marek's disease new castle disease vaccine live marek's disease vector.*** Clarification for this difference is required moreover What does vHVT310 stands for? *Firm has submitted that all three designations have been used by different organization to refer to the same vaccine* • *Bursal Disease-Marek disease Newcastle disease vaccine live Marek's disease vector.* • *SR3 MDV vector expressing NDV antigen and IBD antigen.* • *vHVT310.*
	Decision: Approved as per Innovator's Specification and as per import policy for finished product.	
128.	**Name and address of Importer**	**M/s Saadat International** 117 Habitat Flat Shadman II, Jail Road,

		Lahore
	Detail of DSL	M/s Saadat International Address: 117 Habitat Flat Shadman II, Jail Road, District Lahore Valid till: 12-Jun-2022
	Name and address of Manufacturer	**Marketing Authorization Holder:** M/s Boehringer Ingelheim Vetmedica GmbH Binger Strabe 173, 55216 Ingelheim am Rhein, Germany. **Manufacturer:** M/s Boehringer Ingelheim Animal Health Inc. USA Address: 1168 Airport Parkway, sw, Gainesville– GA. USA
	Name of exporting country	USA
	Brand Name +Dosage Form + Strength	Vaxxitek HVT +IBD+ND
	Diary No. Date of R& I & fee	Dy. No. 1316R&I Dated 14-01-2022 Rs. 150,000/- (Slip No. 470930674615)
	Composition	Each dose contains: SR3 MDV vector expressing NDV antigen and IBD antigen: vHVT310, atleast… 5,696 pfu
	Pharmacological Group	Immunological, Q101AD16
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	18months (store in liquid nitrogen container) Stability studies of three batches at (2^0C-8^0C) for 30months.
	Document Details	• Original legalized certificate of Licensing and Inspection (No. 21-01306) dated March 02, 2021 is submitted by the firm. • Product specific letter of authorization is submitted by the firm.
	Pack size	1000 doses.
	Reference Regulatory Authority Availability	Approved in USA
	Products already registered in Pakistan	Innovax-ND (Marek's Disease - Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector) Turkey Herpesvirus (HVT): minimum of 1810 PFU/dose throughout dating Newcastle Disease Virus- Fusion (F) Protein: minimum of 1802 PFU/dose throughout dating
	Remarks of Evaluator	i. Composition of applied drug as per form 5A is ***SR3 MDV vector expressing NDV antigen and IBD antigen: vHVT310, atleast 5,696 pfu*** however on certificate and licensing and inspection it is ***Bursal Disease-Marek's disease new castle disease vaccine live marek's disease***

		vector. Clarification for this difference is required moreover What does vHVT310 stands for? *Firm has submitted that all three designations have been used by different organization to refer to the same vaccine* • *Bursal Disease-Marek disease Newcastle disease vaccine live Marek's disease vector.* • *SR3 MDV vector expressing NDV antigen and IBD antigen.* • *vHVT310.*
	Decision: Approved as per Innovator's Specification and as per import policy for finished product.	

ADDITIONAL AGENDA 323RD MEETING

129. Products Lumpyvac vaccine and Teylovac vaccine applied by M/s Huzaifa International, Sargodha

The following products of M/s Huzaifa International, Sargodha were approved in various meetings of Registration Board. The details are as under:

Product name and composition	Document Details	Decisions of RB
Lumpyvac (Lumpy Skin Disease vaccine with Diluent) Each 2 ml Dose contains: Attenuated Lumpy skin disease virus (Neethling strain) …. ≥ $10^{3.5}$ $TCID_{50}$	• Original Legalized Free Sale certificate dated 24-02-2022 • Legalized copy of GMP certificate dated 12-02-2019	**Decision of 316th meeting:** Keeping in view legalized GMP certificate and Legalized Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product with "As per Innovator Specifications" subject to compliance of current Import Policy for finished drugs.
TEYLOVAC Vaccine Live attenuated Freeze dried Theileria Annulata cells based vaccine with diluent Each dose of vaccine contains Theileria annulata…...…….≥ $1x10^7$ cells	Legalized Certificate of Pharmaceutical Product (CoPP) NoB028634. issued by Ministry of Agriculture and Forestry, Turkey, dated.01-10-2019 valid till. 10-11-2024.	**Decision of 313th meeting** Registration Board approved the product namely TEYLOVAC Vaccine as product is highly needed for veterinary use in Pakistan.

The firm M/s Huzaifa International, Sargodha has already been granted registration of Lumpyvac Vaccine having Registration No.111128 vide letter No. F.1-5/2022-AD(BD)(M316) dated 25th March 2022, however as per decision of Policy Board in its 41st meeting, the inspection exemption of manufacturer abroad i.e., M/s Vetal Animal Health Products, Turkey was granted for six months to M/s Huzaifa International, Sargodha. The six months' time period has been completed, hence the virtual inspection was conducted.

The virtual inspection of manufacturing facility abroad namely M/s Vetal Hayvan Sagligi Urunleri A.S. Turkey was conducted on 3rd – 4th November, 2022 by the panel of inspectors vide DRAP's letter No. F.8-1/2022-(I&V-I) dated 24th October, 2022. The conclusion and recommendations are as under:

Conclusion

Keeping in view the proceedings of virtual inspection conducted by the panel of inspectors, it was observed that *due to inadequate communication/ weak tools such as internet connectivity, inappropriate cameras, as mostly mobile cameras were used. Proper inspection cameras, borescopes, fiberscopes (communicated vide DRAP letter No.F.3-2/2005-Reg-I(Vol-II) dated 27th September, 2022) were not utilized, hence on this remote virtual inspection the basic system such as manufacturing facility/ Q.C etc were seen but actual manufacturing proceeding Q.C testing, HVAC system functioning etc could not be verified.*
Moreover, it was also observed that Mr. Asim Rauf, the then Additional Director (E&M) Lahore, DRAP and Mr. Abdullah, Additional Director (PE&R), DRAP (co-opted member) had visited the same unit from 24th to 26th September, 2018 when it was newly built, while on official inspection of another unit of M/s Vetal Animal Health Products in Turkey.
It was highlighted in that inspection report that the newly built unit was a state of the art facility in which trial batches were being manufactured and QC testing of vaccines were performed.

Recommendations:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture veterinary vaccines and appeared to comply the GMP requirements. *Hence, the panel recommends that the Registration Board may grant the registration of applied products namely Teylovac and Lumpyvac vaccines to M/s Huzaifa International, Sargodha for six months. However, the panel strongly recommends on-site inspection in order to verify/ ascertain the Good Manufacturing Practices (GMP) of the firm within six months' time period.*

a. As per inspection report, the filling area of both Lumpyvac and Teylovac vaccine was same, as Teylovac is a live protozoal vaccine while Lumpyvac is a live viral vaccine. The firm informed that cleaning validation procedures are performed for same filling line.
The same was discussed and it was decided to send emails to EMA, FAO and USDA dated 29-11-2022 regarding manufacturing requirements of live viral and live protozoal vaccines to be manufactured for animals in the same filling line. Accordingly, emails were sent to relevant authorities and the responses received did not address the query so far, therefore the case may be submitted for further directions if any.
b. As per recommendation of the panel, the Registration of the products namely Teylovac and Lumpyvac vaccines may be granted for six months only (the details are given above).

Decision: Registration Board after thorough deliberation decided to defer the case of Teylovac Vaccine and advised to seek following clarifications:

- **Manufacturing requirements of live protozoal and live viral vaccines in the same filling line as outlined in the inspection report of the firm and also send emails to Turkish veterinary authority i.e., Directorate-General for Animal Health and Veterinary Medicines and OIE –World Organization for Animal Health.**
- **Legal Affair Divion regarding issuance of registration letter for 6 months' time till onsite inspection by the panel.**

130. Product Hepalid (Heparin Sodium) applied by M/s Lab Diagnostic Pvt. Ltd. Rawalpindi approved in 321st meeting of RB

The following product of M/s Lab Diagnostic Pvt. Ltd. Rawalpindi was approved in 321st meeting of Registration board subject to submission of the data/documents by the firm as per detail mentioned below:

Brand Name / Composition	**Shelf life**	**Decision of 321st meeting of RB**

Hepalid 5000IU/ 5ml Injection Each 5ml contains: Heparin sodium: 5000 USP units	36 months Store at 30°C± 2°C	Keeping in view the approval of USFDA (Reference Regulatory Authority), Registration Board approved the product subject to compliance of current Import Policy for finished drugs & submission of valid legalized CoPP issued by USFDA. The firm shall submit the real time stability data before issuance of Registration letter & shelf life will be granted as per the submitted real time stability study data. The Chairman Registration Board is authorized for issuance of letter after submission of said document & data.

The firm submitted 24 months' real time stability study of applied product Hepalid 5ml vial(25000 IU). Previously, the firm submitted stability data of one year & it was decided that one-year shelf life may be issued on the basis of their already submitted data for the product (5mL vial). Now the case is placed before the Board with updated stability data which is of 24 months.

Decision: Keeping in view the submitted stability data of 24 months, Registration Board approved the shelf life of 24 months for applied product Hepalid 25000IU/5ml vial.

131. Application for the grant of Additional Pack of 1000ml of Locally Manufactured Veterinary Vaccine diluent namely VAXI-DROP by M/s Grand pharma (Pvt). Ltd, Rawat.

Following product of M/s Grand Pharma Pvt Ltd, Lahore was deferred in various meetings of Registration Board in 313th, 316th, 320th meeting of RB as per following details;

Name and address of product manufacturer (Applicant)	**M/s Grand Pharma Pvt Ltd** Plot # 5-A, Street No.N-5, RCCI Estate, Rawat, Islamabad
Brand Name +Dosage Form + Strength	Vaxi-drop 1000ml
Type of Form, Diary No. Date of R& I & fee	Form-5 Dy. No.20999 Date:21-8-2020 Rs. 20,000/- Date: 19-8-2020
Composition	Each ml contains: Monobasic Potassium Phosphate : 0.37 mg Disodium Phosphate Dihydrate : 0.72 mg Sodium Chloride : 7.65mg
Pharmacological Group	Diluent for live Avian vaccines
Finished Product Specification	Manufacturer' Spec
Shelf Life	2 Years (15^0C -25^0C)
Document Details	All the undertaking has been submitted by the firm. Copy of DML Copy of inspection report for GMP for viral vaccines section (killed) & Bacterial killed vaccine section.
Pack size & Demanded Price	0.30ml per bird **Decontrolled**
Products already registered in Pakistan	*MS Bac* (M/s Hi-Tech Pharma, Lahore)
Remarks of Evaluator	

Previous Decisions:
Decision of 313th Meeting:

Deferred for submission of method of administration of vaccine and container closer system of diluent.

Decision of 316th Meeting:

Deferred for confirmation of manufacturing facility for the diluents

Decision of 320th Meeting:

Deferred for confirmation of international practices regarding the manufacturing sections requirement for manufacturing of vaccine diluents

In response, the firm has submitted following:

a. The vaccines diluents are sterile water preparations used for diluting & dispensing live vaccines of poultry and livestock which are presented in lyophilized form in a vial of 12-5ml capacity, containing 1000-5000 doses of a live vaccine. The vaccines for livestock and poultry are available in multiple doses format, therefore, to dispense these live vaccines a sterile water-based Diluent preparation is required. These diluents are available in separate packing and already a number of imported and local products have been registered 36ml (1000 doses) for eye-drop usage or 25ml and 50ml (25-50 doses) for sub/ cut injection or 200ml (1000 doses) for sub/ cut injection.
b. The container closure system comprises of an autoclavable polypropylene bottle having rubber caps with aluminum seals.
c. The required equipment for producing and filling/ packing of proposed 1000ml pack size is already available in the production facility of Grand Pharma.
d. The following vaccine diluents are already registered with DRAP:

Vaccine Type	Presentation of Approved Diluents	Administration Route	Doses per vaccine vial	Company
NDV/ IBD/ IBV Live	36ml	Eye Drop/ Spray Drinking water	1000	- Lead pharma (local) - MSD - Elanco
NDV/ IBDV/ IBV live	Bulk RO water	Drinking water	-	Normal Field practice
MD/ CAV Live	200ml	Sub-Cut	1000	- MSD - CEVA
LSD Live	50ml	Sub-Cut	25 & 50	- MSD - Arriah

e. Regarding international practices for the production of diluents, the firm submitted that as per literature, diluents are produced in injectable facilities of a Pharma or Biologics production unit.

Based on the above, it is pointed out that although all types of queries from DRAP in this case have been responded accordingly, however, it has taken more than 2 years to reach to any decision in this case. Such delays are badly affecting our production plans for this product. It is therefore requested that all the queries raised during its evaluation by the Drug Registration Boards, so approval may please be granted at the earliest for production of VAXI-Drop (1000 ml pack size) at Grand Pharma (Pvt) Ltd., Rawat Islamabad, accordingly.

Decision: Registration Board deferred the case and advised BE&R Division to compile data of all such registrations granted to M/s Grand Pharma and place before Registration Board for its consideration.

Item No. III: Division of Quality Assurance & Laboratory Testing

S. NO.	CASE TITLE
AGENDA ITEM NO. 01 - ROUTINE CASES	
1.	MANUFACTURE & SALE OF SUB-STANDARD PROTONIX 40MG TABLETS, BATCH NO. 052 & 069 BY M/S WILSHIRE LABORATORIES (PVT.) LTD., LAHORE.

Case No. I: MANUFACTURE & SALE OF SUB-STANDARD PROTONIX 40MG TABLETS, BATCH NO. 052 & 069 BY M/S WILSHIRE LABORATORIES (PVT.) LTD., LAHORE.

Detail of samples:

Name:	Protonix 40mg Tablet	Protonix 40mg Tablet
Composition:	Each tablet contain 40mg Pantoprazole	Each tablet contain 40mg Pantoprazole
Registration No:	030041	030041
Batch No:	**052**	**069**
Manufacturing Date:	09-17	Jan. 2020
Expiry Date:	08-20	Jan. 2023
Manufactured By:	M/s Wilshire Laboratories (Pvt.) Ltd, Lahore	M/s Wilshire Laboratories (Pvt.) Ltd, Lahore

Summary of the case:

Date	Action
25-04-18	FID-VI, DRAP Karachi visited the premises of M/s Marhaba Medicos, Shop No. 51, Bismillah Market, near New Sabzi Mandi Super Highway, Karachi and took sample of Protonix 40mg Tablets, Batch No.052 on form-3
26-04-2018	The FID-VI, Karachi has forwarded one sealed portion of sample to CDL, Karachi
20-06-2018	The Federal Government Analyst, CDL, Karachi declared the sample as of Sub-standard quality **on the basis of dissolution** vide test/analysis report R.KQ.310/2018. Details of report are: ***Description:*** *Yellow colored, circular shaped enteric coated tablets.* ***Identification:*** *Pantoprazole Sodium identified.* ***Dissolution test:*** ***Does not comply.*** ***Uniformity of dosage unit By Weight Variation:*** *Complies.* ***Assay for Pantoprazole Sodium:*** *Determined amount/tablet: 38.2609mg* *Stated amount/tablet: 40mg* *Percentage: 95.7%* *Limits: 90.0% to 110.0% Complies.* ***Remarks:*** *The sample is of **"Substandard"** quality under the Drugs Act, 1976.*
26-06-2018	The area FID-VI, Karachi served an explanation letter to M/s Wilshire Laboratories (Pvt.) Ltd, Lahore.
06-07-2018	M/s Wilshire Laboratories (Pvt.) Ltd, Lahore submitted their reply vide letter wherein *they have stated that*

	"They received the sealed portion of their product Protonix 40mg Tablets (Samples quantity of 30 tablets) while Batch No/Mfg Date/Exp Date was not visible on sample pack. We also receive the sample after 41 days after picking the sample which is violation of Section 19 (3) of the Drugs Act 1976. As guidelines of the Drugs Act 1976 were not followed which is illegal and the said procedure is null and void in the eyes of law. The sample dispatched to us remained in transit during very hot months of May and June while no temperature and humidity conditions were maintained. Storage conditions are not mentioned on the report where the sample was stored after receipt and we fail to understand as the sample remained untested for 54 days. We had provided reference standard to CDL but we are not sure whether our provided reference standard was used for testing or CDL arranged reference standard from some other source because USP 40 method was used. So, USP reference standard must have been used. Please provide a copy of reference standard of Pantoprazole USP. As per USP method of testing, 68 tablets are required while the sample sent to CDL, Karachi contain 30 tablets so how the required tests can be performed with provided sample."
06-03-2019	Show cause notice has been issued to the technical staff/management of the firm vide letter no. 03-49/2018-(QC).
13-03-2019	The firm submitted their reply with reference number WL/OC/S-267
16-05-2019	**They have been appeared in 289th Meeting of Registration Board and** re-iterated points already submitted in showcause reply and the firm requested for retesting of drug product. **Decision:** *Registration Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided that the Board's portion of the sample shall be retested from appellate laboratory, NIH, Islamabad.*
17-07-2019	The subject cited sample was received in Appellate laboratory, NIH, Islamabad as per decision of the Registration Board in its 289th meeting.
16-09-2019	National Institute of Health, Islamabad also declared the sample of Protonix 40mg Tablets, Batch No. 052 by M/s Wilshire Laboratories (Pvt.) Ltd Lahore as of "**Sub-standard"** quality vide their test report No. 017-M/2019 **on the basis Dissolution test**. Results are reproduced as under: **Description:** Light yellow, circular, biconvex enteric coated tablets plain on both sides packed in blister packing further contained in an outer carton. **Identification:** Pantoprazole sodium identified. **Wt. Variation:** Complies with USP 39 **Dissolution test:** **Determined.** **Limit:** **Acid stage** 12.7% of label amount Not more than 10% (Q) of the label amount. **Buffer stage** 36.32% of the label amount Not more than 75% (Q) of the label amount.

	(Does not comply with USP 39) **Assay:** **Stated:** **Found:** **Limit:** **Percentage:** Pentoprazole sodium 40mg/tablet 41.40mg/tablet 90-110% 103.51% Sesquihydrate **(Complies with USP 39)** In the opinion of the undersigned the sample is of sub-standard quality as defined in the Drug Act, 1976 for the reason(s) given below. **Dissolution test:** **Determined.** **Limit:** **Acid stage** 12.7% of label amount Not more than 10% (Q) of the label amount. **Buffer stage** 36.32% of the label amount Not more than 75% (Q) of the label amount. **(Does not comply with USP 39)**
14-02-2019	The Appellate Laboratory, NIH, Islamabad declared the said sample as Misbranded and Substandard quality (on the basis of dissolution) vide test report No.04-M/2019.
12-11-2019	Show cause notice has been served to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-49/2018-(QC).
18-11-2019	M/s Wilshire Laboratories (Pvt.) Ltd., Lahore vide reference No.WL/OC/S-344 submitted their reply and is reproduced as under: • *Our DRAP registration letter for Protonix 40mg tablet is with MS Specification" and same was mentioned on all packing materials of Protonix 40mg tablets, B# 052. We have provided method of testing with "**Manufacturer Specification**" to NIH but we are surprised to learn that our product has been tested on USP-39.* • *In USP monograph of pantoprazole sodium delayed release tablets, label cliaim is pantoprazol ($C_{16}H_{15}F_2N_3O_4S$) and identification test is derived on the basis of retention time of peaks from assay, while in both CDL and NIH reports the identification test claim is pantoprazole sodium which is violation of USP claim.* • *In CDL report assay test result is 95.7% while in NIH report assay test result is 103.51% which deviate more than 5% of ICH stability limit.* • *In dissolution test, Test1 is not mentioned in NIH report.* • *Acid stage failure is not mentioned in CDL report while the NIH declared the product fail on both stages.* • *In calculation formula applied on both stages is not precisely mentioned for given six batches as reading deviates from individual reports as well average results.* • *In tolerance of dissolution acid stage Pantoprazole Sodium is written which further entitles that there is calculation errors in this report.* • *As per our continuous improvement policy, we have already worked regarding dissolution of our product. We have complete product development and stability data available with us and can be provided in personal hearing.*

	In light of the above mentioned submissions, it is respectfully and humbly prayed that the report by CDL and NIH be held to be based upon misreading and non reading of evidence and consequently a nullity in the eyes of the law; Furthermore, the show cause notice dated 12-11-2019 be held to be not based upon the law and facts and be withdrawn/dismissed; *You are most humbly requested to provide us with a right of hearing; any other relief as deemed just, appropriate and equitable by the learned Board may also most graciously be granted.*
08-01-2019	They appeared before the Board in 293rd meeting of Registration Board and stated that they still have concerns on the analytical method of NIH, Islamabad. Furthermore, they have made necessary improvements and shifted their product from manufacturer's specifications to Pharmacopoeal specifications. They further requested to analyze their product from individual laboratory. **Decision of 293rd meeting of Registration Board.** The case was presented before the Registration Board in its 293rd meeting held on 08th January, 2019 and the Board after detailed discussion and deliberations considering the test reports of CDL & NIH, Islamabad unanimously decided as under: **i.** Suspension of the Registration of the said product for six (06) months or till the verification of root cause analysis and satisfactory report by the panel whichever is later. **ii.** Corrective and preventive action (CAPA) by the firm and product development data. **iii.** Product Specific Inspection including verification of product development data and confirmation of CAPA by the following panel: ➢ Mr. Iftikhar Ahmad Member Registration Board. ➢ Area Federal Inspector of Drugs. ➢ Hafiz Ahsan AD, PEC.
21-04-2020	Decision was communicated.
15-03-2021	**PSI Report** In compliance to the decision of 293rd Meeting of Registration Board, FID, DRAP, Lahore has submitted the PSI report of M/s. Wilshire Labs (Pvt.) Ltd., K}Lahore. The inspection was conducted for verification of root cause analysis, corrective and preventive action (CAPA) and product development data of their product Protonix 40mg Tablet containing Pantoprazole sodium sesquihydrate. ***Conclusion:*** *Based on the inspection proceedings, such as verification of documents, interaction with management e.t.c the panel concludes that the company has not given root cause analysis and rectified their dissolution problem through product development process. The firm only shifted their testing method from Mfg spec to UPS. However, the management made commitment and also agreed to make necessary improvements in procedures.* ***Recommendation:*** *Keeping in view the above observations the panel could not verify the product development process and root cause analysis conducted by the firm at this stage. However, the final*

	conclusion would be based upon the test report results received from the Central Drugs Laboratory, Karachi. *Hence the panel recommend that the decision of the Drug Registration Board for suspension of registration of Protonix 40mg Tablets may remain intact.*
26-06-2019	PSI report was presented in 308th meeting of Registration Board. **Decision of 308th Meeting of Registration Board** The Board after thorough deliberations, considering the facts of the case, report submitted by the FID, DRAP, Lahore decided as i. The suspension of registration of Protonix 40mg Tablet remain intact. ii. The Comparative Dissolution Profile of the product with innovator's product will be submitted by the firm for consideration of the Board
08-09-2021	The decision has been communicated to the firm.
14-09-2021	M/s. Wilshire Labs (Pvt.) Ltd., Lahore vide Ref # WL/OC/S-597 submitted that they used Dissolution Test 2 for testing of our product. They also requested for personal hearing.
16-11-2021 to 18-11-2021	**Proceedings and Decision of 313th Meeting of Registration Board.** The Board after thorough deliberations, considering the facts of the case, decided to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Wilshire Labs (Pvt.) Ltd., Lahore and called them for personal hearing before Registration Board**.**
15-03-2022 to 16-03-2022	**Proceedings and Decision of 316th Meeting of Registration Board:** **a)** Mr. Faisal Javed (Plant Head) and Mr. Muhammad Omer (Quality Control Manager) of M/s. Wilshire Labs (Pvt.) Ltd., Lahore appeared before the Board and endorsed/re-iterated their already submitted stance. **b)** The Board after considering the facts of the case and after thorough deliberations decided as follows: i) The sample of Protonix 40mg Batch No. 069 shall be sent for Appellate testing as per USP specification (Dissolution Test-Type 2) ii) Firm shall develop product as per guidelines approved in 293rd meeting and will share data with QA Division. iii) Registration of product 'Protonix 40mg Tablet' (Reg# 030041) shall remain suspended till compliance of both above points.
27-07-2022	The decision of the Board has been communicated to firm and the Board's portion submitted in NIH as per decision.
13-10-2022	Test report of the sample has been received from NIH where in it is concluded as: *"The sample is of Sub-standard quality on the basis of test performed."*

Decision:

The board after detailed deliberation decided to issue ***Show Cause notice to M/s. Wilshire Labs (Pvt.) Ltd., Lahore on manufacturing and sale of substandard Protonix 40mg Tablets, Batch No. 052 & 069 and provide personal hearing under Section 42 of the Drugs Act, 1976 and rules framed thereunder.***

Meeting ended with vote of thanks to and from the chair.